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South Carolina Department of Health
and Environmental Control

Guidance Document

For Preparing
Quality Assurance Project Plans
for
Environmental Monitoring Projects/Studies

Office of Quality Assurance

Bureau of Environmental Services

Environmental Quality Control

April 2000

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QAPP) as an important tool for project managers and planners to document the type and quality of data needed for environmental decisions and to provide a blueprint for collecting and assessing those data from environmental programs. The development, review, approval, and implementation of the QAPP is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA or funded by EPA to develop and operate management structures and processes for ensuring that data collected or compiled for use in Agency decisions are of the type and quality needed and expected for their intended use. The QAPP is the integral part of the fundamental principals and practices that form the foundation of the South Carolina Department of Health and Environmental Control (SCDHEC) Quality System.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision- making. This depends significantly on the adequacy of the QAPP and its effective implementation. Proper planning must occur to ensure that all the needs of the user are defined with quality in mind.

This document presents specifications and instructions for the information that must be contained in a Quality Assurance Project Plan for environmental data operations performed by SCDHEC or on its behalf by extramural organizations. It discusses the procedures for review, approval, implementation, and revision of QAPPs. Users of this document should assume that all of the elements described herein are required in the QAPP unless otherwise directed by SCDHEC.

This document contains the same requirements as found in the *EPA QA/G-5, Guidance for Quality Assurance Project Plans* and *EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations.* Other information cited complies with mandatory Quality Management Programs as described in:

EPA QA/R-1 *EPA Quality Systems Requirements for Environmental Programs*

EPA QA/R-2 *EPA Requirements for Quality Management Plans*

It is the intent that the guide will assist the project manager in preparing the QAPP for submittal to the Department for approval. A thorough and well-written QAPP will help expedite the approval process to ensure that all applicable elements are addressed. All projects must have an approved QAPP before environmental monitoring may commence. Questions regarding this document may be directed to:

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Chapter I

Introduction

Overview

This document presents detailed guidance on how to develop a Quality Assurance Project Plan (QAPP) for environmental data operations performed by or for the SC Department of Health and Environmental Control. It discusses how to address and implement the specifications in *EPA QA/R-5, Requirements for QA Project Plans for Environmental Data Operations.*

The QAPP is the critical planning tool for any environmental data collection operation because it documents how quality assurance (QA) and quality control (QC) activities will be implemented during the life cycle of a program, project, or task. QA is a system of management activities designed to ensure that the data produced by the operation will be of the type and quality needed and expected by the data user. It aids in supporting management decisions in a resource-efficient manner.

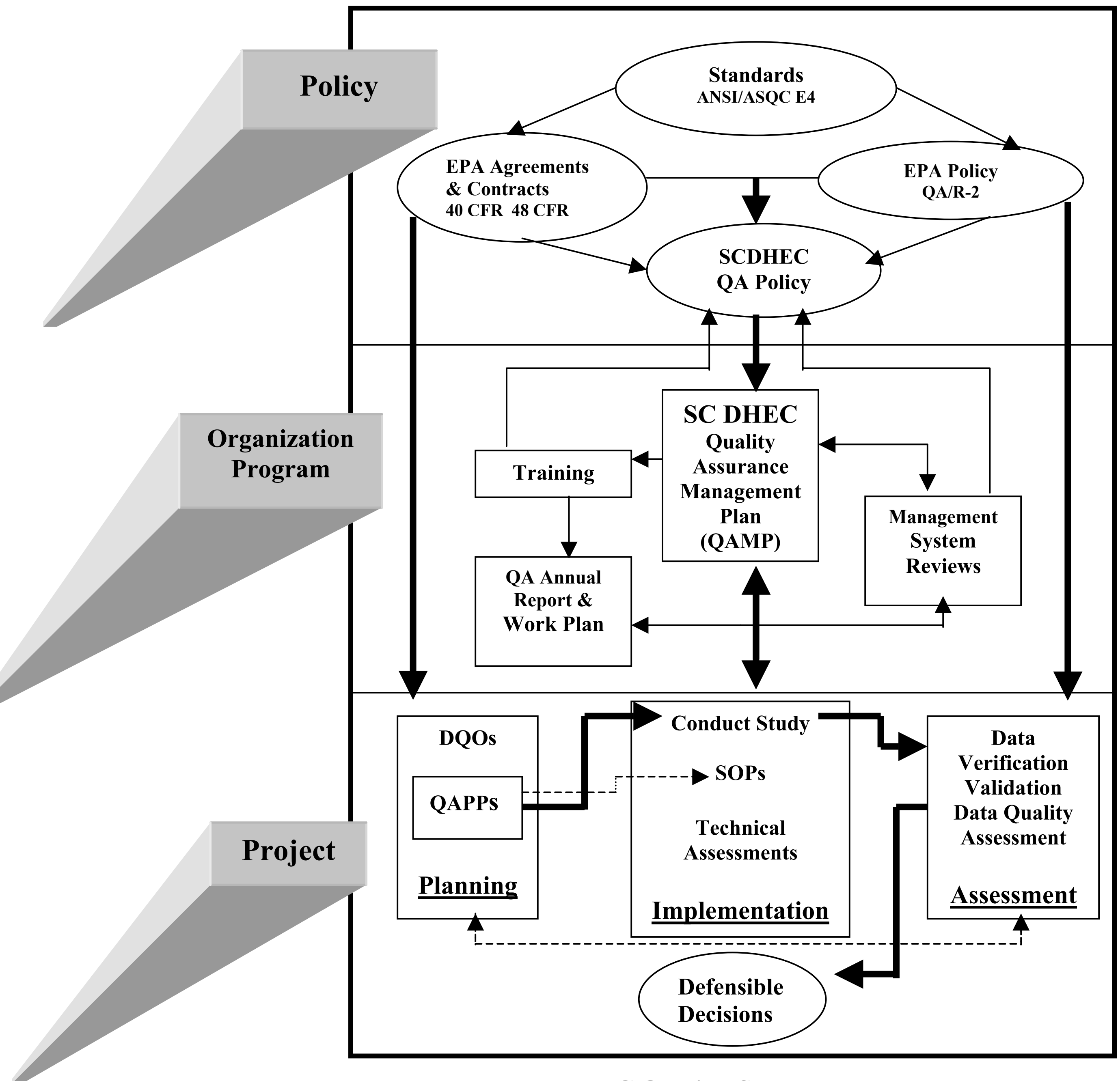
The QAPP is the key component of the SCDHEC Quality System as shown in Figure 1. It is the principal product of a systematic planning process. It integrates all technical and quality aspects for the life-cycle of the project, including planning, implementation, and assessment.

A QAPP is composed of four sections of project-related information called "groups", which are subdivided into specific detailed "elements." The degree to which each QAPP element should be addressed will be dependent on the specific project and can range from "not applicable" to extensive documentation. This document provides a discussion and background of the elements of a QAPP that will typically be necessary. The final decision on the specific need for these elements for the project-specific QAPP will be made by the sponsoring SCDHEC Bureau/Program and/or Office of Quality Assurance.

Purpose

The SCDHEC Quality System is a structured management system describing policies, objectives, principles, organization, responsibilities, accountability, and implementation plan for ensuring quality in its work processes, products, and services.

EPA and SCDHEC policy require that all projects involving the generation, acquisition, and use of environmental data be planned and documented and have an Agency-approved QAPP prior to the start of data collection. The primary purpose of the QAPP is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project, all within a single document. The QAPP should be detailed enough to provide a clear description for every aspect of the project and include information for every member of the project staff including samplers, lab staff, and data reviewers. Effective implementation of the QAPP assists project managers in keeping projects on schedule and within the resource budget.



The DHEC Quality System

Figure 1

Chapter II

EPA/SCDHEC Policy on Quality Assurance Project Plans

EPA Policy

All work performed by extramural organizations on behalf of or funded by EPA that involves the collection or use of environmental data in Agency(SCDHEC) programs shall be implemented in accordance with a SCDHEC approved QAPP developed from a systematic planning process based on the "graded approach."[1] **No work** funded by EPA and involving the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems, shall be implemented without an **approved QAPP** available prior to start of the work.

SCDHEC Policy

"When this Agency (DHEC) enters a cooperative agreement with another agency, the lead agency (Project Manager) will be responsible for generating the project study plan(unless otherwise agreed upon). Data quality objectives must be clearly established to ensure the validity of the data collected. A QA Project Plan is necessary and should be completed in accordance with the guidance documents and the Agency's Quality Assurance Management Plan (QAMP)"[2].

Any laboratory producing data for a Program's direct utilization must have Standard Operating Procedures in accordance with U.S. EPA methods, *Standard Methods for the Examination of Water and Wastewater*, and/or approved methods. The laboratory organization, structure, areas of responsibility, must be available for review by the Program reviewing data. The organization must be certified by the State's Office of Environmental Laboratory Certification (where certified methods exist). Any laboratory that sub-contracts to another lab must assure that the affected laboratory has the required certification. The Project Officer should state in the QAPP that a contracting lab must ensure the approved certification status of the subcontracted lab. The data received must be in a format determined by the Program area and must be of acceptable quality-scientifically valid, defensible, and of known and acceptable precision and accuracy.

Applicability

These QAPP requirements apply to all environmental programs that acquire, generate, or compile environmental data on behalf of or funded by EPA/SCDHEC. These operations include work performed through contracts, interagency agreements, and assistance agreements (e.g., cooperative agreements, grants). QAPPs shall be prepared,

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[1] EPA QA/R-5, Page 5. A graded approach is the process of basing the level of application of managerial controls applied to an item or work on the intended use of the results and the degree of confidence needed in the quality of the results.

[2] Quality Assurance Management Plan for SCDHEC, Section 6.1, Page 15.

reviewed, and approved in accordance with the specifications contained in this document for the collection activity unless explicitly superseded by the regulation.

Special Requirements

In some cases, it may be necessary to add special requirements to the QAPP. The SCDHEC organization sponsoring the work has the authority to define any special requirements beyond those listed in this requirements document. If none or specified, the QAPP shall address all required elements. Attached documentation, such as an approved Work Plan, Standard Operating Procedures(SOPs), etc., may be referenced in response to a particular QAPP element. This is encouraged to reduce the size of the QAPP and the time required to prepare it. The QAPP should also address related QA planning documentation from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task. In any case, all referenced documents must be attached to the QAPP or be placed on file with the appropriate SCDHEC office and available for referencing as needed.

Responsibilities

QAPPs may be prepared by SCDHEC personnel, contractors, cooperative agreement holders(university, environmental firm, etc.), or another State agency under an interagency agreement. **Except where specifically delegated, all QAPPs prepared by non-SCDHEC organizations must be approved by SCDHEC before implementation.** Writing a QAPP is often a collaborative effort within an organization, or among organizations, and depends on the technical expertise, writing skills, knowledge of the project, and availability of the staff. Organizations are encouraged to involve technical project staff and the QA Office in this effort to ensure that the QAPP has adequate detail and coverage.

Approvals

None of the environmental data collection work addressed by the QAPP may be started until the initial QAPP has been approved by the DHEC Sponsoring Program and State Quality Assurance Management Officer (SQAMO) or designee. In some cases, DHEC may grant conditional or partial approval to permit some of the work to begin while noncritical deficiencies in it are being resolved. The QA Officer should be consulted to determine the nature of the work that may continue and the type of work that may be performed under a conditionally approved QAPP. The following approvals are possible:

- **Full Approval:** No remaining identified defiencies exist in the QAPP and the project may commence.

- **Partial Approval:** Some activities identified in the QAPP still contain critical deficiencies while other activities are acceptable. If the acceptable activities are not contingent upon the completion of the activities with deficiencies, a *partial approval* is granted for those activities to proceed. Work should continue to resolve the portions of the QAPP that are deficient.

- **Conditional Approval:** Approval of the QAPP or portions thereof will be granted upon agreement to implement specific conditions, specific language, etc. by parties required to approve the QAPP in order to expedite the initiation of field work. In most situations, the *conditional approval* is upgraded to final *approval* upon receipt, review, and sign off by all parties of the revised/additional QAPP pages.

Once approved, the organization performing the work is responsible for implementing the QAPP. This responsibility includes ensuring all personnel involved in the work have copies of or access to the approved QAPP along with all other necessary planning documents. Personnel should understand their responsibilities prior to the start of data generation activities.

Revisions

Organizations are responsible for keeping the QAPP current when changes to technical aspects of the project change. QAPPs must be revised to incorporate such changes. **Any revisions or additions to the QAPP must be re-approved by SCDHEC and distributed to all participants in the project.**

Chapter III

QAPP Preparation

The QAPP is the formal document describing in comprehensive detail the necessary QA/QC and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP must provide sufficient detail to demonstrate that:

- the project technical and quality objectives (Data Quality Objectives) are identified and agreed upon;

- the intended measurements or data acquisition methods are appropriate for achieving project objectives;

- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and

- any limitations on the use of the data can be identified and documented.

In order to be effective, the QAPP must specify the level or degree of QA/QC needed for the particular environmental data operation. Because this will vary according to the purpose and type work being done, SCDHEC will evaluate QA/QC applied to a project commensurate with :

- purpose of the environmental data collection

- type of work to be done

- intended use of the data

An analysis sheet is provided to assist the QAPP preparer and QA Office in determining the level and detail of information required in the QAPP. Answering some basic questions should provide guidance in addressing all applicable elements and determining which QAPP protocol to follow. See Figure 2 on page 6-3.

Format

There are two basic formats to use in writing the Quality Assurance Project Plan. They are the <u>Proposal Quality Assurance Plan (PQAP)</u> and the more detailed <u>QA Project Plan(QAPP).</u> Depending on the level of detailed required, the decision to accept the less formal PQAP is left to the DHEC Project Officer and SQAMO/QA Officer.

The Proposal Quality Assurance Plan Document

The Proposal Quality Assurance Plan is a brief document that encompasses elements of the Quality Management Plan (QMP) and the QA Project Plan (QAPP) and presents these elements in a less formal format, including a narrative. The PQAP may be applied to small data collection projects, small grants for basic or exploratory research, community/student education, and similar work of limited scope and duration. The PQAP is used frequently in responses to proposals and applications for extramural agreements to demonstrate the offeror/applicant's capabilities for satisfying QA/QC requirements in extramural agreement regulations. See Appendix A.

The PQAP shall include or address:

- a project title sheet with signature and date of project officer

- a project description, including the purpose of the work, the data collection activities to be performed, and how the environmental data produced will be used;

- a statement of the project objectives, including the primary goals, expected level of confidence in the resulting data, and criteria for successful completion of the work;

- a description of the sampling and analytical design (experimental design) of the project, including identification of critical and non-critical aspects of the project, sampling and analytical methods to be used, calibration requirements for instruments (as appropriate), and relevant method performance criteria;

- a description of the process for the handling and custody of samples, including sample identification, preservation, transportation, storage, and final disposal;

- a listing of the proposed start and ending dates for the project with key milestones and interim deliverables, as appropriate, identified;

- a listing of key project staff and their roles and responsibilities

- a description of how quality will be assured during the project, including the use of performance evaluations, audits, surveillance, and other assessment procedures;

- procedures for data verification and validation (including any statistical analyses used), and how corrective actions will be implemented

- identify any needed reports on QA/QC activities

Quality Assurance Project Plan Document

The QAPP document is the most frequently used format and applies to most environmental data collection work. It will apply to contracts, interagency agreements, large cooperative agreements and grants, etc. that include post-award environmental monitoring, sampling, and analysis activities and long term studies. The QAPP must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. See Appendix A and C.

The elements of a QAPP are categorized into "groups" according to their function. **All applicable elements defined in this guide must be addressed. If an element is not applicable, state this in the QAPP.** The elements are:

Group A Project Management

This group of elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

- A1 Title and Approval Sheet
- A2 Table of Contents
- A3 Distribution List
- A4 Project/Task Organization
- A5 Problem Definition/Background
- A6 Project/Task Description
- A7 Data Quality Objectives and Criteria for Measurement Data
- A8 Special Training Requirements/Certification
- A9 Documentation and Records

Group B Measurement/Data Acquisition

This group of QAPP elements covers all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, data handling, and QC are employed and are documented.

- B1 Sampling Process Design (Experimental Design)
- B2 Sampling Methods Requirements
- B3 Sample Handling and Custody Requirements
- B4 Analytical Methods Requirements
- B5 Quality Control Requirements

B6 Instrument/Equipment Testing, Inspection, Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements (Non-direct Measurements)
B10 Data Management

Group C **<u>Assessment/Oversight</u>**

This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.

C1 Assessments and Response Actions
C2 Reports to Management

Group D **<u>Data Validation and Usability</u>**

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

D1 Data Review, Validation, and Verification Requirements
D2 Validation and Verification Methods
D3 Reconciliation with User Requirements

SCDHEC QAPP FORMAT SELECTION

Project/Study Title:____
Sponsoring Authority/Program____
Project Manager____
Project Date: ___________________________

Purpose of the Environmental Data Collection (Check all that apply):

___ Enforcement/compliance
___ Agency research and development
___ Rulemaking (Agency decisions)
___ Community education/involvement
___ Cooperative agency agreements/ initiatives
___ University/High School research study
___ Other____

Type of Work to be done (Check all that apply):

___ Pollutant monitoring
___ Site characterization
___ Environmental research/ analytical method (parameter) development
___ Comparability studies
___ SCDHEC contracted analyses
___ Other____

Intended Use of the Data (Check all that apply):

___ Compliance determination
___ Selection of remedial technology
___ Development of environmental regulations
___ Development of EPA/SCDHEC standards, limits
___ Community education/involvement—brochures, best practices, etc.
___ DHEC Program use
___ University/School research only
___ Other____

If items are checked in any of the above categories that will involve externally generated project/study data being used by the Department in decision making, compliance and enforcement, establishing agency regulations, standards or limits, or a program's direct use, then the <u>QAPP format</u> will be required.

OQA **Figure 2** February 2000

CHAPTER IV

QAPP ELEMENTS

A PROJECT MANAGEMENT

The following project management elements address the procedural aspects of project development and what to include in the QAPP project background, task description, and quality objectives elements. Summaries from R-5 are contained in the text box following the title of each element.

A1 TITLE AND APPROVAL SHEET

Include title of plan; name of the organization(s); and names, titles, signatures of appropriate approving officials, and their approval dates.

The title and approval sheet includes the title of the QAPP; the name(s) of the organization(s) implementing the project; and the names, titles, and signatures, and the signature dates of the appropriate approving officials. The approving officials typically include: the organization's Technical Project Manager, the organization's Quality Assurance Officer or Manager, the EPA (or other funding agency) Technical Project Manager/Project Officer, Laboratory Directors, Laboratory QA Officers, the EPA (or other funding agency) Quality Assurance Officer or Manager, and other key staff, such as the QA Officer of the prime contractor when a QAPP is prepared by a subcontractor organization.

The purpose of the approval sheet is to enable officials to document their approval of the QAPP. The title page (along with the organization chart) also identifies the key project officials for the work. The title and approval sheet should also indicate the date of the revision and a document number, if appropriate.

A2 TABLE OF CONTENTS AND DOCUMENT CONTROL FORMAT

List sections, figures, tables, references, and appendices.

The table of contents lists all the elements, references, and appendices contained in a QAPP, including a list of tables and a list of figures that are used in the text. The major headings for most QAPPs should closely follow the list of required elements; an example is shown in Figure 2. While the exact format of the QAPP does not have to follow the sequence given here, it is generally more convenient to do so, and it provides a standard format to the QAPP reviewer. Moreover, consistency in the format makes the document more familiar to users, who can expect to find a specific item in the same place in every QAPP.

The table of contents of the QAPP may include a document control component. This information should appear in the upper right-hand corner of each page of the QAPP when document control format is desired. For example:

Project No. or Name ___________ Element or Section No. _________ Revision No. _________________ Revision Date ________________ Section/Element Page ___ of _____

This component, together with the distribution list (see element A3), facilitates control of the document to help ensure that the most current QAPP is in use by all project participants. Each revision of the QAPP should have a different revision number and date.

A3 DISTRIBUTION LIST

List all the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all persons who are responsible for implementation (including managers), the QA managers, and representatives of all groups involved.

All the persons and document files designated to receive copies of the QAPP, and any planned future revisions, need to be listed in the QAPP. This list, together with the document control information, will help the project manager ensure that all key personnel in the implementation of the QAPP have up-to-date copies of the plan. A typical distribution list appears in Figure 2.

A4 PROJECT/TASK ORGANIZATION

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include principal data users, the decision makers, the project QA manager, and all persons responsible for implementation.

Ensure that the project QA manager is independent of the unit generating the data.

Provide a concise organization chart showing the relationships and the lines of communication among all project participants; other data users who are outside of the organization generating the data; and any subcontractor relationships relevant to environmental data operations.

A4.1 Purpose/Background

The purpose of the project organization is to provide EPA and other involved parties with a clear understanding of the role that each party plays in the investigation or study and to provide the lines of authority and reporting for the project.

A4.2 Roles and Responsibilities

The specific roles, activities, and responsibilities of participants, as well as the internal lines of authority and communication within and between organizations, should be detailed. The position of the QA Manager or QA Officer should be described. Include the principal data users, the decision maker, project manager, QA manager, and all persons responsible for implementation of the QAPP. Also included should be the person responsible for maintaining the QAPP and any individual approving

CONTENTS

Section

Distribution List

N. Wentworth, EPA/ORD (Work Assignment Manager)*
B. Waldron, EPA/ORD (QA Manager)
J. Warren, State University (Principal Investigator)
T. Dixon, State University (QA Officer)
G. Johnson, State University (Field Activities)
F. Haeberer, State University (Laboratory Activities)
B. Odom, State University (Data Management)
E. Renard, ABC Laboratories (Subcontractor Laboratory)
P. Lafornara, ABC Laboratories (QA Manager Subcontractor Laboratory)

*indicates approving authority

Figure 2. An Example of a Table of Contents and a Distribution List

deliverables other than the project manager. A concise chart showing the project organization, the lines of responsibility, and the lines of communication should be presented; an example is given in Figure 3. For complex projects, it may be useful to include more than one chart—one for the overall project (with at least the primary contact) and others for each organization. Where direct contact between project managers and data users does not occur, such as between a project consultant for a potentially responsible party and the EPA risk assessment staff, the organization chart should show the route by which information is exchanged.

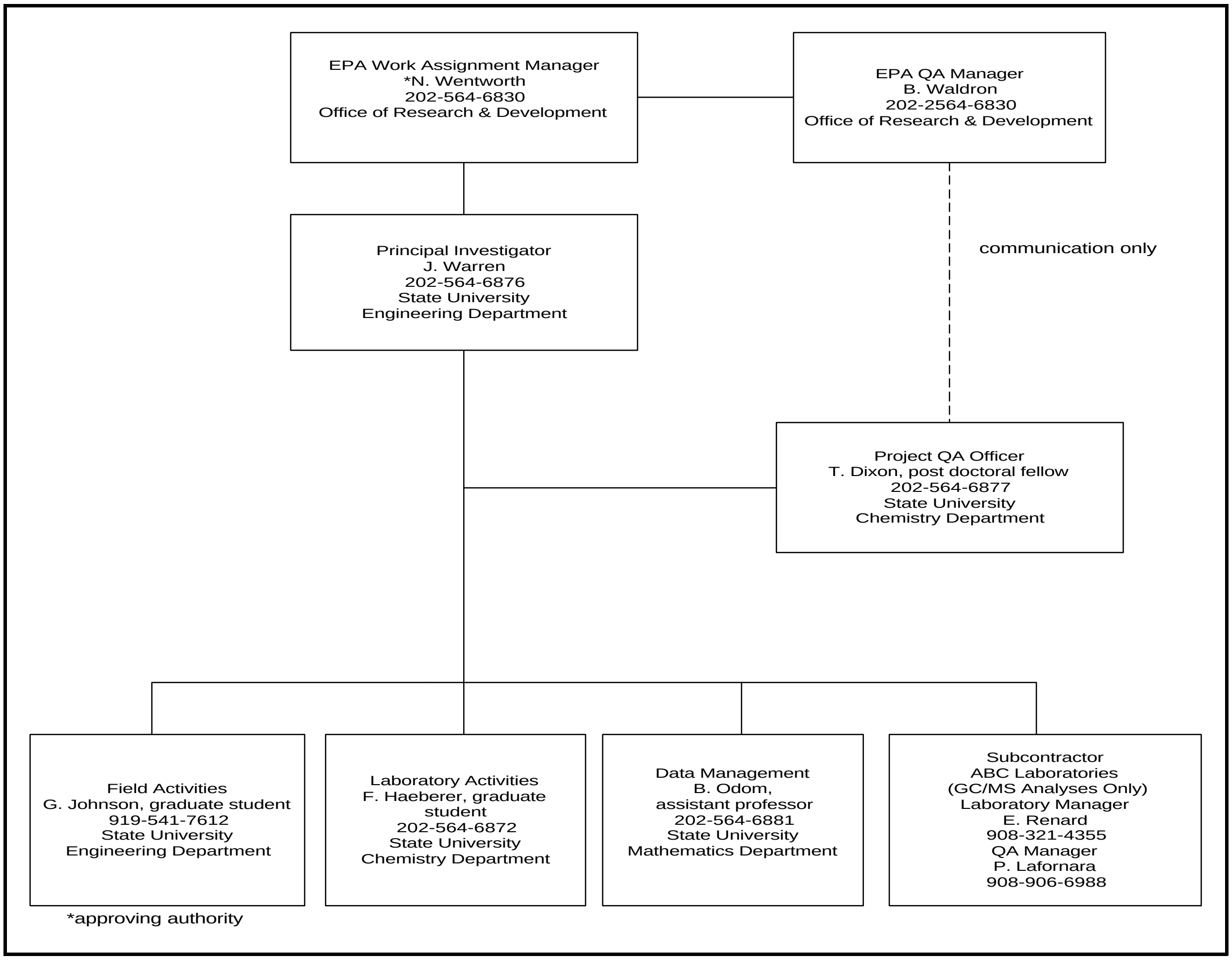

Figure 3. An Example of a Project Organization Chart

A5 PROBLEM DEFINITION/BACKGROUND

State the specific problem to be solved or decision to be made and include sufficient background information to provide a historical and scientific perspective for this particular project.

A5.1 Purpose/Background

The background information provided in this element will place the problem in historical perspective, giving readers and users of the QAPP a sense of the project's purpose and position relative to other project and program phases and initiatives.

A5.2 Problem Statement and Background

This discussion must include enough information about the problem, the past history, any previous work or data, and any other regulatory or legal context to allow a technically trained reader to make sense of the project objectives and activities. This discussion should include:

- a description of the problem as currently understood, indicating its importance and programmatic, regulatory, or research context;
- a summary of existing information on the problem, including any conflicts or uncertainties that are to be resolved by the project;
- a discussion of initial ideas or approaches for resolving the problem there were considered before selecting the approach described in element A6, “Project/Task Description”; and
- the identification of the principal data user or decision maker (if know).

Note that the problem statement is the first step of the DQO Process and the decision specification is the second step of the DQO Process.

A6 PROJECT/TASK DESCRIPTION AND SCHEDULE

Provide a description of the work to be performed and the schedule for implementation. Include measurements that will be made during the course of the project; applicable technical, regulatory, or program-specific quality standards, criteria, or objectives; any special personnel and equipment requirements; assessment tools needed; a schedule for work to be performed; and project and quality records required, including types of reports needed.

A6.1 Purpose/Background

The purpose of the project/task description element is to provide the participants with a background understanding of the project and the types of activities to be conducted, including the measurements that will be taken and the associated QA/QC goals, procedures, and timetables for collecting the measurements.

A6.2 Description of the Work to be Performed

(1) **Measurements that are expected during the course of the project.** Describe the characteristic or property to be studied and the measurement processes and techniques that will be used to collect data.

(2) **Applicable technical quality standards or criteria.** Cite any relevant regulatory standards or criteria pertinent to the project. For example, if environmental data are collected to test for compliance with a permit limit standard, the standard should be cited and the numerical limits should be given in the QAPP. The DQO Process refers to these limits as "action levels," because the type of action taken by the decision maker will depend on whether the measured levels exceed the limit (Step 5 of the DQO Process).

(3) **Any special personnel and equipment requirements that may indicate the complexity of the project.** Describe any special personnel or equipment required for the specific type of work being planned or measurements being taken.

(4) **The assessment techniques needed for the project.** The degree of quality assessment activity for a project will depend on the project's complexity, duration, and objectives. A discussion of the timing of each planned assessment and a brief outline of the roles of the different parties to be involved should be included.

(5) **A schedule for the work performed.** The anticipated start and completion dates for the project should be given. In addition, this discussion should include an approximate schedule of important project milestones, such as the start of environmental measurement activities.

(6) **Project and quality records required, including the types of reports needed.** An indication of the most important records should be given.

A7 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

Describe the project quality objectives and measurement performance criteria.

A7.1 Purpose/Background

The purpose of this element is to document the DQOs of the project and to establish performance criteria for the mandatory systematic planning process and measurement system that will be employed in generating the data.

A7.2 Specifying Quality Objectives

This element of the QAPP should discuss the desired quality of the final results of the study to ensure that the data user's needs are met. The Agency strongly recommends using the DQO Process (see Figure 4), a systematic procedure for planning data collection activities, to ensure that the right type, quality, and quantity of data are collected to satisfy the data user's needs. DQOs are qualitative and quantitative statements that:

- clarify the intended use of the data,
- define the type of data needed to support the decision,
- identify the conditions under which the data should be collected, and
- specify tolerable limits on the probability of making a decision error due to uncertainty in the data.

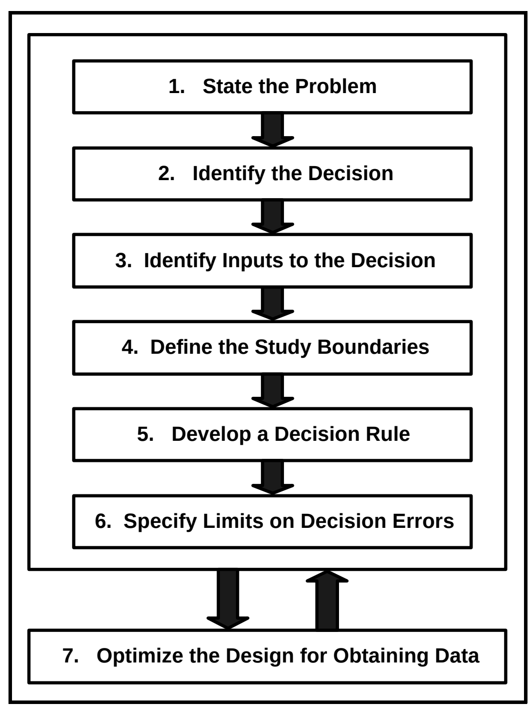

Figure 4. The DQO Process

Data Quality Indicators (DQIs) can be evolved from DQOs for a sampling activity through the use of the DQO Process (Appendix D). Figure 4 shows the seven steps of the DQO Process, which is explained in detail in EPA QA/G-4, *Guidance for the Data Quality Objectives Process.*

Appendix A.4 provides a crosswalk between the requirements of the QAPP and the DQO outputs. The QAPP should include a reference for a full discussion of the proposed DQOs.

For exploratory research, sometimes the goal is to develop questions that may be answered by subsequent work. Therefore, researchers may modify activities advocated in QA/G-4 to define decision errors (see EPA QA/G-4R, *Data Quality Objectives for Researchers*).

A7.3 Specifying Measurement Performance Criteria

While the quality objectives state what the data user's needs are, they do not provide sufficient information about how these needs can be satisfied. The specialists who will participate in generating the data need to know the measurement performance criteria that must be satisfied to achieve the overall quality objectives. One of the most important features of the QAPP is that it links the data user's quality objectives to verifiable measurement performance criteria. Although the level of rigor with which this is done and documented will vary widely, this linkage represents an important advancement in the implementation of QA. Once the measurement performance criteria have been established, sampling and analytical methods criteria can be specified under the elements contained in Group B.

A8 SPECIAL TRAINING REQUIREMENTS/CERTIFICATION

Identify and describe any specialized training or certification requirements and discuss how such training will be provided and how the necessary skills will be assured and documented.

A8.1 Purpose/Background

The purpose of this element is to ensure that any specialized training requirements necessary to complete the projects are known and furnished and the procedures are described in sufficient detail to ensure that specific training skills can be verified, documented, and updated as necessary.

A8.2 Training

Requirements for specialized training for nonroutine field sampling techniques, field analyses, laboratory analyses, or data validation should be specified. Depending on the nature of the environmental data operation, the QAPP may need to address compliance with specifically mandated training requirements. For example, contractors or employees working at a Superfund site need specialized training as mandated by the Occupational Safety and Health (OSHA) regulations. If hazardous materials are moved offsite, compliance with the training requirements for shipping hazardous materials as mandated by the Department of Transportation (DOT) in association with the International Air Transportation Association may be necessary. This element of the QAPP should show that the management and project teams are aware of specific health and safety needs as well as any other organizational safety plans.

A8.3 Certification

Usually, the organizations participating in the project that are responsible for conducting training and health and safety programs are also responsible for ensuring certification. Training and certification should be planned well in advance for necessary personnel prior to the implementation of the project.

All certificates or documentation representing completion of specialized training should be maintained in personnel files.

A9 DOCUMENTATION AND RECORDS

Itemize the information and records that must be included in the data report package and specify the desired reporting format for hard copy and electronic forms, when used.

Identify any other records and documents applicable to the project, such as audit reports, interim progress reports, and final reports, that will be produced.

Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

A9.1 Purpose/Background

This element defines which records are critical to the project and what information needs to be included in reports, as well as the data reporting format and the document control procedures to be used. Specification of the proper reporting format, compatible with data validation, will facilitate clear, direct communication of the investigation.

A9.2 Information Included in the Reporting Packages

The selection of which records to include in a data reporting package must be determined based on how the data will be used. Different "levels of effort" require different supporting QA/QC documentation. For example, organizations conducting basic research have different reporting requirements from organizations collecting data in support of litigation or in compliance with permits. When possible, field and laboratory records should be integrated to provide a continuous reporting track. The following are examples of different records that may be included in the data reporting package.

A9.2.1 <u>Field Operation Records</u>

The information contained in these records documents overall field operations and generally consists of the following:

- *Sample collection records.* These records show that the proper sampling protocol was performed in the field. At a minimum, this documentation should include the names of the persons conducting the activity, sample number, sample collection points, maps and diagrams, equipment/method used, climatic conditions, and unusual observations. Bound field notebooks are generally used to record raw data and make references to prescribed procedures and changes in planned activities. They should be formatted to include pre-numbered pages with date and signature lines.

- *Chain-of-custody records*. Chain-of-custody records document the progression of samples as they travel from the original sampling location to the laboratory and finally to their disposal area. (See Appendix C for an example of a chain-of-custody checklist.)

- *QC sample records.* These records document the generation of QC samples, such as field, trip, and equipment rinsate blanks and duplicate samples. They also include documentation on sample integrity and preservation and include calibration and standards' traceability documentation capable of providing a reproducible reference point. Quality control sample records should contain information on the frequency, conditions, level of standards, and instrument calibration history.

- *General field procedures.* General field procedures record the procedures used in the field to collect data and outline potential areas of difficulty in gathering specimens.

- *Corrective action reports.* Corrective action reports show what methods were used in cases where general field practices or other standard procedures were violated and include the methods used to resolve noncompliance.

If applicable, to show regulatory compliance in disposing of waste generated during the data operation, procedures manifest and testing contracts should be included in the field procedures section.

A9.2.2 <u>Laboratory Records</u>

The following list describes some of the laboratory-specific records that should be compiled if available and appropriate:

- *Sample Data.* These records contain the times that samples were analyzed to verify that they met the holding times prescribed in the analytical methods. Included should be the overall number of samples, sample location information, any deviations from the SOPs, time of day, and date. Corrective action procedures to replace samples violating the protocol also should be noted.

- *Sample Management Records.* Sample management records document sample receipt, handling and storage, and scheduling of analyses. The records verify that the chain-of-custody and proper preservation were maintained, reflect any anomalies in the samples (such as receipt of damaged samples), note proper log-in of samples into the laboratory, and address procedures used to ensure that holding time requirements were met.

- *Test Methods.* Unless analyses are performed exactly as prescribed by SOPs, this documentation will describe how the analyses were carried out in the laboratory. This includes sample preparation and analysis, instrument standardization, detection and reporting limits, and test-specific QC criteria. Documentation demonstrating laboratory proficiency with each method used could be included.

- *QA/QC Reports.* These reports will include the general QC records, such as initial demonstration of capability, instrument calibration, routine monitoring of analytical performance, calibration verification, etc. Project-specific information from the QA/QC checks such as blanks (field, reagent, rinsate, and method), spikes (matrix, matrix spike replicate, analysis matrix spike, and surrogate spike), calibration check samples (zero check, span check, and mid-range check), replicates, splits, and so on should be included in these reports to facilitate data quality analysis.

A9.2.3 Data Handling Records

These records document protocols used in data reduction, verification, and validation. Data reduction addresses data transformation operations such as converting raw data into reportable quantities and units, use of significant figures, recording of extreme values, blank corrections, etc. Data verification ensures the accuracy of data transcription and calculations, if necessary, by checking a set of computer calculations manually. Data validation ensures that QC criteria have been met.

A9.3 Data Reporting Package Format and Documentation Control

The format of all data reporting packages must be consistent with the requirements and procedures used for data validation and data assessment described in Sections B, C, and D of the QAPP. All individual records that represent actions taken to achieve the objective of the data operation and the performance of specific QA functions are potential components of the final data reporting package. This element should discuss how these various components will be assembled to represent a concise and accurate record of all activities impacting data quality. The discussion should detail the recording medium for the project, guidelines for hand-recorded data (e.g., using indelible ink), procedures for correcting data (e.g., single line drawn through errors and initialed by the responsible person), and documentation control. Procedures for making revisions to technical documents should be clearly specified and the lines of authority indicated.

A9.4 Data Reporting Package Archiving and Retrieval

The length of storage for the data reporting package may be governed by regulatory requirements, organizational policy, or contractual project requirements. This element of the QAPP should note the governing authority for storage of, access to, and final disposal of all records.

A9.5 References

Kanare, Howard M. 1985. *Writing the Laboratory Notebook.* Washington, DC: American Chemical Society.

U.S. Environmental Protection Agency. 1993. *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring.* EPA/821/B-93/001.

B MEASUREMENT/DATA ACQUISITION

B1 SAMPLING PROCESS DESIGN (EXPERIMENTAL DESIGN)

Describe the experimental design or data collection design for the project. **Classify all measurements as critical or non-critical.**

B1.1 Purpose/Background

The purpose of this element is to describe all the relevant components of the experimental design; define the key parameters to be estimated; indicate the number and type of samples expected; and describe where, when, and how samples are to be taken. The level of detail should be sufficient that a person knowledgeable in this area could understand how and why the samples will be collected. This element provides the main opportunity for QAPP reviewers to ensure that the "right" samples will be taken. Strategies such as stratification, compositing, and clustering should be discussed, and diagrams or maps showing sampling points should be included. Most of this information should be available as outputs from the final steps of the planning (DQO) process.

In addition to describing the design, this element of the QAPP should discuss the following:

- a schedule for project sampling activities,
- a rationale for the design (in terms of meeting DQOs),
- the sampling design assumptions,
- the procedures for locating and selecting environmental samples,
- a classification of measurements as critical or noncritical, and
- the validation of any nonstandard sampling/measurement methods.

Elements B1.2 through B1.8 address these subjects.

B1.2 Scheduled Project Activities, Including Measurement Activities

This element should give anticipated start and completion dates for the project as well as anticipated dates of major milestones, such as the following:

- schedule of sampling events;
- schedule for analytical services by offsite laboratories;
- schedule for phases of sequential sampling (or testing), if applicable;
- schedule of test or trial runs; and
- schedule for peer review activities.

The use of bar charts showing time frames of various QAPP activities to identify both potential bottlenecks and the need for concurrent activities is recommended.

B1.3 Rationale for the Design

The objectives for an environmental study should be formulated in the planning stage of any investigation. The requirements and the rationale of the design for the collection of data are derived from the quantitative outputs of the DQO Process. The type of design used to collect data depends heavily on the key characteristic being investigated. For example, if the purpose of the study is to estimate overall average contamination at a site or location, the characteristic (or parameter) of interest would be the mean level of contamination. This information is identified in Step 5 of the DQO Process. The relationship of this parameter to any decision that has to be made from the data collected is obtained from Steps 2 and 3 of the DQO Process (see Figure 4).

The potential range of values for the parameter of interest should be considered during development of the data collection methodology and can be greatly influenced by knowledge of potential ranges in expected concentrations. For example, the number of composite samples needed per unit area is directly related to the variability in potential contaminant levels expected in that area.

The choice between a probability-based (statistical) data collection design or a nonrandom (judgmental) data collection methodology depends on the ultimate use of the data being collected. This information is specified in Steps 5 and 6 of the DQO Process. Adherence to the data collection design chosen in Step 7 of the DQO Process directly affects the magnitude of potential decision error rates (false positive rate and false negative rate) established in Step 6 of the DQO Process. Any procedures for coping with unanticipated data collection design changes also should be briefly discussed.

B1.4 Design Assumptions

The planning process usually recommends a specific data collection method (Step 7 of the DQO Process), but the effectiveness of this methodology rests firmly on assumptions made to establish the data collection design. Typical assumptions include the homogeneity of the medium to be sampled (for example, sludge, fine silt, or wastewater effluent), the independence in the collection of individual samples (for example, four separate samples rather than four aliquots derived from a single sample), and the stability of the conditions during sample collection (for example, the effects of a rainstorm during collection of wastewater from an industrial plant). The assumptions should have been considered during the DQO Process and should be summarized together with a contingency plan to account for exceptions to the proposed sampling plan. An important part of the contingency plan is documenting the procedures to be adopted in reporting deviations or anomalies observed after the data collection has been completed. Examples include an extreme lack of homogeneity within a physical sample or the presence of analytes that were not mentioned in the original sampling plan. Chapter 1 of EPA QA/G-9 provides an overview of sampling plans and the assumptions needed for their implementation. EPA QA/G-5S provides guidance on the construction of sampling plans to meet the requirements generated by the DQO Process.

B1.5 Procedures for Locating and Selecting Environmental Samples

The most appropriate plan for a particular sampling application will depend on: the practicality and feasibility (e.g., determining specific sampling locations) of the plan, the key characteristic (the parameter established in Step 5 of the DQO Process) to be estimated, and the implementation resource requirements (e.g., the costs of sample collection, transportation, and analysis).

This element of the QAPP should also describe the frequency of sampling and specific sample locations (e.g., sample port locations and traverses for emissions source testing, well installation designs for groundwater investigations) and sampling materials. When decisions on the number and location of samples will be made in the field, the QAPP should describe how these decisions will be driven whether by actual observations or by field screening data. When locational data are to be collected, stored, and transmitted, the methodology used must be described (or referenced) and include the following:

- procedures for finding prescribed sample locations,
- contingencies for cases where prescribed locations are inaccessible,
- location bias and its assessment, and
- procedures for reporting deviations from the sampling plan.

When appropriate, a map of the sample locations should be provided and locational map coordinates supplied. EPA QA/G-5S provides nonmandatory guidance on the practicality of constructing sampling plans and references to alternative sampling procedures.

B1.6 Classification of Measurements as Critical or Noncritical

All measurements should be classified as critical (i.e., required to achieve project objectives or limits on decision errors, Step 6 of the DQO Process) or noncritical (for informational purposes only or needed to provide background information). Critical measurements will undergo closer scrutiny during the data gathering and review processes and will have first claim on limited budget resources. It is also possible to include the expected number of samples to be tested by each procedure and the acceptance criteria for QC checks (as described in element B5, "Quality Control Requirements").

B1.7 Validation of Any Nonstandard Methods

For nonstandard sampling methods, sample matrices, or other unusual situations, appropriate method validation study information may be needed to confirm the performance of the method for the particular matrix. The purpose of this validation information is to assess the potential impact on the representativeness of the data generated. For example, if qualitative data are needed from a modified method, rigorous validation may not be necessary. Such validation studies may include round-robin studies performed by EPA or by other organizations. If previous validation studies are not available, some level of single-user validation study or ruggedness study should be performed during the project and included as part of the project's final report. This element of the QAPP should clearly reference any available validation study information.

B2 SAMPLING METHODS REQUIREMENTS

Describe the procedures for collecting samples and identify the sampling methods and equipment. Include any implementation requirements, support facilities, sample preservation requirements, and materials needed. Describe the process for preparing and decontaminating sampling equipment, including disposing decontamination by-products; selecting and preparing sample containers, sample volumes, preservation methods, and maximum holding times for sampling and/or analysis.

Describe specific performance requirements for the method. Address what to do when a failure in the sampling occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.

B2.1 Purpose/Background

Environmental samples should reflect the target population and parameters of interest. As with all other considerations involving environmental measurements, sampling methods should be chosen with respect to the intended application of the data. Just as methods of analysis vary in accordance with project needs, sampling methods can also vary according to these requirements. Different sampling methods have different operational characteristics, such as cost, difficulty, and necessary equipment. In addition, the sampling method can materially affect the representativeness, comparability, bias, and precision of the final analytical result.

In the area of environmental sampling, there exists a great variety of sample types. It is beyond the scope of this document to provide detailed advice for each sampling situation and sample type. Nevertheless, it is possible to define certain common elements that are pertinent to many sampling situations with discrete samples (see EPA QA/G-5S).

If a separate sampling and analysis plan is required or created for the project, it should be included as an appendix to the QAPP. The QAPP should simply refer to the appropriate portions of the sampling and analysis plan for the pertinent information and not reiterate information.

B2.2 Describe the Sample Collection, Preparation, and Decontamination Procedures

(1) *Select and describe appropriate sampling methods from the appropriate compendia of methods.* For each parameter within each sampling situation, identify appropriate sampling methods from applicable EPA regulations, compendia of methods, or other sources of methods that have been approved by EPA. When EPA-sanctioned procedures are available, they will usually be selected. When EPA-sanctioned procedures are not available, standard procedures from other organizations and disciplines may be used. A complete description of non-EPA methods should be provided in (or attached to) the QAPP. Procedures for sample homogenization of nonaqueous matrices may be described in part (2) as a technique for assuring sample representativeness. In addition, the QAPP should specify the type of sample to be collected (e.g., grab, composite, depth-integrated, flow- weighted) together with the method of sample preservation.

(2) *Discuss sampling methods' requirements.* Each medium or contaminant matrix has its own characteristics that define the method performance and the type of material to be sampled. Investigators should address the following:

- actual sampling locations,
- choice of sampling method/collection,
- delineation of a properly shaped sample,
- inclusion of all particles within the volume sampled, and
- subsampling to reduce the representative field sample into a representative laboratory aliquot.

Having identified appropriate and applicable methods, it is necessary to include the requirements for each method in the QAPP. If there is more than one acceptable sampling method applicable to a particular situation, it may be necessary to choose one from among them. DQOs should be considered in choosing these methods to ensure that: a) the sample accurately represents the portion of the environment to be characterized, b) the sample is of sufficient volume to support the planned chemical analysis, and c) the sample remains stable during shipping and handling.

(3) *Describe the decontamination procedures and materials.* Decontamination is primarily applicable in situations of sample acquisition from solid, semi-solid, or liquid media, but it should be addressed, if applicable, for continuous monitors as well. The investigator must

consider the appropriateness of the decontamination procedures for the project at hand. For example, if contaminants are present in the environmental matrix at the 1% level, it is probably unnecessary to clean sampling equipment to parts-per-billion (ppb) levels. Conversely, if ppb-level detection is required, rigorous decontamination or the use of disposable equipment is required. Decontamination by-products must be disposed of according to EPA policies and the applicable rules and regulations that would pertain to a particular situation, such as the regulations of OSHA, the Nuclear Regulatory Commission (NRC), and State and local governments.

B2.3 Identify Support Facilities for Sampling Methods

Support facilities vary widely in their analysis capabilities, from percentage-level accuracy to ppb-level accuracy. The investigator must ascertain that the capabilities of the support facilities are commensurate with the requirements of the sampling plan established in Step 7 of the DQO Process.

B2.4 Describe Sampling/Measurement System Failure Response and Corrective Action Process

This section should address issues of responsibility for the quality of the data, the methods for making changes and corrections, the criteria for deciding on a new sample location, and how these changes will be documented. This section should describe what will be done if there are serious flaws with the implementation of the sampling methodology and how these flaws will be corrected. For example, if part of the complete set of samples is found to be inadmissable, how replacement samples will be obtained and how these new samples will be integrated into the total set of data should be described.

B2.5 Describe Sampling Equipment, Preservation, and Holding Time Requirements

This section includes the requirements needed to prevent sample contamination (disposable samplers or samplers capable of appropriate decontamination), the physical volume of the material to be collected (the size of composite samples, core material, or the volume of water needed for analysis), the protection of physical specimens to prevent contamination from outside sources, the temperature preservation requirements, and the permissible holding times to ensure against degradation of sample integrity.

B2.6 References

Publications useful in assisting the development of sampling methods include:

Solid and Hazardous Waste Sampling

U.S. Environmental Protection Agency. 1986. *Test Methods for Evaluating Solid Waste (SW-846).* 3rd Ed., Chapter 9.

U.S. Environmental Protection Agency. 1985. *Characterization of Hazardous Waste Sites - A Methods Manual. Vol. I, Site Investigations.* EPA-600/4-84-075. Environmental Monitoring Systems Laboratory. Las Vegas, NV.

U.S. Environmental Protection Agency. 1984. *Characterization of Hazardous Waste Sites - A Methods Manual. Vol. II, Available Sampling Methods.* EPA-600/4-84-076. Environmental Monitoring Systems Laboratory. Las Vegas, NV.

U.S. Environmental Protection Agency. 1987. *A Compendium of Superfund Field Operations Methods.* NTIS PB88-181557. EPA/540/P-87/001. Washington, DC.

Ambient Air Sampling

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. I, Principles*. EPA 600/9-76-005. Section 1.4.8 and Appendix M.5.6.

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. II,* EPA 600/R-94-038b. Sections 2.0.1 and 2.0.2 and individual methods.

U.S. Environmental Protection Agency. 1984. *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air.* EPA/600-4-84-41. Environmental Monitoring Systems Laboratory. Research Triangle Park, NC. *Supplement:* EPA-600-4-87-006. September 1986.

Source Testing (Air)

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. III,* EPA 600/R-94-038c. Section 3.0 and individual methods.

Water/ Ground Water

U.S. Environmental Protection Agency. *Handbook: Ground Water.* Cincinnati, OH. EPA/625/6-87/016. March 1987.

U.S. Environmental Protection Agency. *RCRA Ground Water Monitoring Technical Enforcement Guidance Document.* Washington, DC. 1986.

U.S. Environmental Protection Agency. *Standard Methods for the Examination of Water and Wastewater.* 16th ed. Washington, DC. 1985.

Acid Precipitation

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. V*, EPA 600/94-038e.

Meteorological Measurements

U.S. Environmental Protection Agency. 1989. *Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. IV*, EPA 600/4-90-003.

Radioactive Materials and Mixed Waste

U.S. Department of Energy. 1989. *Radioactive-Hazardous Mixed Waste Sampling and Analysis: Addendum to SW-846.*

Soils and Sediments

U.S. Environmental Protection Agency. 1985. *Sediment Sampling Quality Assurance User's Guide.* NTIS PB85-233542. EPA/600/4-85/048. Environmental Monitoring Systems Laboratory. Las Vegas, NV.

U.S. Environmental Protection Agency. 1989. *Soil Sampling Quality Assurance User's Guide.* EPA/600/8-89/046. Environmental Monitoring Systems Laboratory. Las Vegas, NV.

Barth, D.S., and T.H. Starks. 1985. *Sediment Sampling Quality Assurance User's Guide.* EPA/600-4-85/048. Prepared for Environmental Monitoring and Support Laboratory. Las Vegas, NV.

Statistics, Geostatistics, and Sampling Theory

Myers, J.C. 1997. *Geostatistical Error Measurement.* New York: Van Nostrand Reinhold.

Pitard, F.F. 1989. *Pierre Gy's Sampling Theory and Sampling Practice. Vol I and II.* Boca Raton, FL: CRC Press.

Miscellaneous

American Chemical Society Joint Board/Council Committee on Environmental Improvement. 1990. *Practical Guide for Environmental Sampling and Analysis, Section II. Environmental Analysis.* Washington, DC.

ASTM Committee D-34. 1986. *Standard Practices for Sampling Wastes from Pipes and Other Point Discharges.* Document No. D34.01-001R7.

Keith, L. 1990. *EPA's Sampling and Analysis Methods Database Manual.* Austin, TX: Radian Corp.

Keith, L. 1991. *Environmental Sampling and Analysis: A Practical Guide.* Chelsea, MI: Lewis Publishers, Inc.

B3 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

Describe the requirements and provisions for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules.

Include examples of sample labels, custody forms, and sample custody logs.

B3.1 Purpose/Background

This element of the QAPP should describe all procedures that are necessary for ensuring that:

(1) samples are collected, transferred, stored, and analyzed by authorized personnel;

(2) sample integrity is maintained during all phases of sample handling and analyses; and

(3) an accurate written record is maintained of sample handling and treatment from the time of its collection through laboratory procedures to disposal.

Proper sample custody minimizes accidents by assigning responsibility for all stages of sample handling and ensures that problems will be detected and documented if they occur. A sample is in custody if it is in actual physical possession or it is in a secured area that is restricted to authorized personnel. The level of custody necessary is dependent upon the project's DQOs. While enforcement actions necessitate stringent custody procedures, custody in other types of situations (i.e., academic research) may be primarily concerned only with the tracking of sample collection, handling, and analysis.

Sample custody procedures are necessary to prove that the sample data correspond to the sample collected, if data are intended to be legally defensible in court as evidence. In a number of situations, a complete, detailed, unbroken chain of custody will allow the documentation and data to substitute for the physical evidence of the samples (which are often hazardous waste) in a civil courtroom. Some statutes or criminal violations may still necessitate that the physical evidence of sample containers be presented along with the custody and data documentation.

An outline of the scope of sample custody--starting from the planning of sample collection, field sampling, sample analysis to sample disposal--should also be included. This discussion should further stress the completion of sample custody procedures, which include the transfer of sample custody from field personnel to lab, sample custody within the analytical lab during sample preparation and analysis, and data storage.

B3.2 Sample Custody Procedure

The QAPP should discuss the sample custody procedure at a level commensurate with the intended use of the data. This discussion should include the following:

(1) List the names and responsibilities of all sample custodians in the field and laboratories.

(2) Give a description and example of the sample numbering system.

(3) Define acceptable conditions and plans for maintaining sample integrity in the field prior to and during shipment to the laboratory (e.g., proper temperature and preservatives).

(4) Give examples of forms and labels used to maintain sample custody and document sample handling in the field and during shipping. An example of a sample log sheet is given in Figure 5; an example sample label is given in Figure 6.

(5) Describe the method of sealing shipping containers with chain-of-custody seals. An example of a seal is given in Figure 7.

(6) Describe procedures that will be used to maintain the chain of custody and document sample handling during transfer from the field to the laboratory, within the laboratory, and among contractors. An example of a chain-of-custody record is given in Figure 8.

(7) Provide for the archiving of all shipping documents and associated paperwork.

(8) Discuss procedures that will ensure sample security at all times.

(9) Describe procedures for within-laboratory chain-of-custody together with verification of the printed name, signature, and initials of the personnel responsible for custody of samples, extracts, or digests during analysis at the laboratory. Finally, document disposal or consumption of samples should also be described. A chain-of-custody checklist is included in Appendix C to aid in managing this element.

Minor documentation of chain-of-custody procedures is generally applicable when:

- Samples are generated and immediately tested within a facility or site; and
- Continuous rather than discrete or integrated samples are subjected to real- or near real-time analysis (e.g., continuous monitoring).

The discussion should be as specific as possible about the details of sample storage, transportation, and delivery to the receiving analytical facility.

FOR________ SURVEY________ SAMPLE LOG SHEET NO.________ DATE________

TYPE OF SAMPLE________ **SAMPLER:** *(Signature)*________ **A N A L Y S E S R E Q U I R E D**

STATION NUMBER	STATION DESCRIPTION	TIME SAMPLE TAKEN	TOTAL VOLUME	TYPE CONTAINER	PRESERVATIVE	NUTRIENTS	BOD	COD	TOC	TOTAL SOLIDS	SUSPENDED SOLIDS	ALKALINITY	DO	pH*	CONDUCTIVITY*	TEMPERATURE*	TOTAL COLIFORM	FECAL COLIFORM	TURBIDITY	OIL AND GREASE	METALS	BACTI	PESTICIDES	HERB	TRACE ORGANICS	PHENOL	CYANIDE

REMARKS

***Field Measurements**

U.S. EPA, NEIC Director

Figure 5. An Example of a Sample Log Sheet

(Name of Sampling Organization)

Sample Description: ______________________________
____

Plant: ____________ Location: ____________
Date: ____________ ____________
Time: ____________ ____________
Media: ____________ Station: ____________
Sample Type: ____________ Preservative: ____________

Sampled By: ______________________________

Sample ID No.: ______________________________

Lab No. ______________________________

Remarks: ____________

Figure 6. An Example of a Sample Label

Signature ____________

Date ____________

CUSTODY SEAL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CUSTODY SEAL

____
Date

____
Signature

Figure 7. An Example of a Custody Seal

				SAMPLERS *(Signature)*							
STATION NUMBER	STATION LOCATION	DATE	TIME	SAMPLE TYPE			SEQ NO.	NO. OF CONTAINERS	ANALYSIS REQUIRED		
				WATER		AIR					
				Comp	Grabx						

Relinquished by: *(Signature)*	Received by: *(Signature)*	DATE/TIME
Relinquished by: *(Signature)*	Received by: *(Signature)*	DATE/TIME
Relinquished by: *(Signature)*	Received by: *(Signature)*	DATE/TIME
Received by: *(Signature)*	Received by Mobile Laboratory for field analysis: *(Signature)*	DATE/TIME

Received by: *(Signature)*	DATE/TIME	Received for Laboratory by:	DATE/TIME
Method of Shipment:			

Distribution: Original - Accompany Shipment
1 Copy - Survey Coordinator Field Files

Figure 8. An Example of a Chain-of-Custody Record

B4 ANALYTICAL METHODS REQUIREMENTS

Identify the analytical methods and equipment required, including sub-sampling or extraction methods, laboratory decontamination procedures and materials (such as the case of hazardous or radioactive samples), waste disposal requirements (if any), and specific performance requirements for the method.

Identify analytical methods by number, date, and regulatory citation (as appropriate). If a method allows the user to select from various options, then the method citations should state exactly which options are being selected. For non-standard methods, such as unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results.

Address what to do when a failure in the analytical system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.

Specify the laboratory turnaround time needed, if important to the project schedule. Specify whether a field sampling and/or laboratory analysis case narrative is required to provide a complete description of any difficulties encountered during sampling or analysis.

B4.1 Purpose/Background

The choice of analytical methods will be influenced by the performance criteria, Data Quality Objectives, and possible regulatory criteria. If appropriate, a citation of analytical procedures may be sufficient if the analytical method is a complete SOP. For other methods, it may suffice to reference a procedure (i.e., from *Test Methods for Evaluating Solid Waste,* SW-846) and further supplement it with the particular options/variations being used by the lab, the detection limits actually achieved, the calibration standards and concentrations used, etc. If the procedure is unique or an adaption of a "standard" method, complete analytical and sample preparation procedures will need to be attached to the QAPP.

Specific monitoring methods and requirements to demonstrate compliance traditionally were specified in the applicable regulations and/or permits. However, this approach is being replaced by the Performance-Based Measurement System (PBMS). PBMS is a process in which data quality needs, mandates, or limitations of a program or project are specified and serve as a criterion for selecting appropriate methods. The regulated body selects the most cost-effective methods that meet the criteria specified in the PBMS. Under the PBMS framework, the performance of the method employed is emphasized rather than the specific technique or procedure used in the analysis. Equally stressed in this system is the requirement that the performance of the method be documented and certified by the laboratory that appropriate QA/QC procedures have been conducted to verify the performance. PBMS applies to physical, chemical, and biological techniques of analysis performed in the field as well as in the laboratory. PBMS does not apply to the method-defined parameters.

The QAPP should also address the issue of the quality of analytical data as indicated by the data's ability to meet the QC acceptance criteria. This section should describe what should be done if the calibration check samples exceed the control limits due to mechanical failure of the instrumentation, a drift in the calibration curve occurs, or if a reagent blank indicates contamination. This section should also indicate the authorities responsible for the quality of the data, the protocols for making changes and implementing corrective actions, and the methods for reporting the data and its limitations.

Laboratory contamination from the processing of hazardous materials such as toxic or radioactive samples for analysis and their ultimate disposal should be a considered during the planning stages for selection of analysis methods. Safe handling requirements for project samples in the laboratory with appropriate decontamination and waste disposal procedures should also be described.

B4.2 Subsampling

If subsampling is required, the procedures should be described in this QAPP element, and the full text of the subsampling operating procedures should be appended to the QAPP. Because subsampling may involve more than one stage, it is imperative that the procedures be documented fully so that the results of the analysis can be evaluated properly.

B4.3 Preparation of the Samples

Preparation procedures should be described and standard methods cited and used where possible. Step-by-step operating procedures for the preparation of the project samples should be listed in an appendix. The sampling containers, methods of preservation, holding times, holding conditions, number and types of all QA/QC samples to be collected, percent recovery, and names of the laboratories that will perform the analyses need to be specifically referenced.

B4.4 Analytical Methods

The citation of an analytical method may not always be sufficient to fully characterize a method because the analysis of a sample may require deviation from a standard method and selection from the range of options in the method. The SOP for each analytical method should be cited or attached to the QAPP, and all deviations or alternative selections should be detailed in the QAPP.

The matrix containing the subject analytes often dictates the sampling and analytical methods. Gaseous analytes often must be concentrated on a trap in order to collect a measurable quantity. If the matrix is a liquid or a solid, the analytes usually must be separated from it using various methods of extraction. Sometimes the analyte is firmly linked by chemical bonds to other elements and must be subjected to digestion methods to be freed for analysis.

Often the selected analytical methods may be presented conveniently in one or several tables describing the matrix, the analytes to be measured, the analysis methods, the type, the precision/accuracy data, the performance acceptance criteria, the calibration criteria, and etc. Appendix C contains a checklist of many important components to consider when selecting analytical methods.

B4.5 References

Greenberg, A.E., L.S. Clescer, and A. D. Eaton, eds. 1992. *Standard Methods for the Examination of Water and Wastewater. 18th ed.* American Public Health Association. Water Environment Federation.

U.S. Environmental Protection Agency. 1996. *Quality Control: Variability in Protocols.* EPA/600/9-91/034. Risk Reduction Engineering Laboratory. U.S. EPA. Cincinnati, OH.

U.S. Environmental Protection Agency. *Test Methods for Evaluating Solid Waste.* SW-846. Chapter 2, "Choosing the Correct Procedure."

B5 QUALITY CONTROL REQUIREMENTS

Identify required measurement QC checks for both the field and the laboratory. State the frequency of analysis for each type of QC check, and the spike compounds sources and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference the procedures to be used to calculate each of the QC statistics.

B5.1 Purpose/Background

QC is "the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer." QC is both corrective and proactive in establishing techniques to prevent the generation of unacceptable data, and so the policy for corrective action should be outlined. This element will rely on information developed in section A7, "Quality Objectives and Criteria for Measurement Data," which establishes measurement performance criteria.

B5.2 QC Procedures

This element documents any QC checks not defined in other QAPP elements and should reference other elements that contain this information where possible. Most of the QC acceptance limits of EPA methods are based on the results of interlaboratory studies. Because of improvements in measurement methodology and continual improvement efforts in individual laboratories, these acceptance limits may not be stringent enough for some projects. In some cases, acceptance limits are based on intralaboratory studies (which often result in narrower acceptance limits than those based on interlaboratory limits), and consultation with an expert may be necessary. Other elements of the QAPP that contain related sampling and analytical QC requirements include:

- **Sampling Process Design** (B1), which identifies the planned field QC samples as well as procedures for QC sample preparation and handling;

- **Sampling Methods Requirements** (B2), which includes requirements for determining if the collected samples accurately represent the population of interest;

- **Sample Handling and Custody Requirements** (B3), which discusses any QC devices employed to ensure samples are not tampered with (e.g., custody seals) or subjected to other unacceptable conditions during transport;

- **Analytical Methods Requirements** (B4), which includes information on the subsampling methods and information on the preparation of QC samples in the sample matrix (e.g., splits, spikes, and replicates); and

- **Instrument Calibration and Frequency** (B7), which defines prescribed criteria for triggering recalibration (e.g., failed calibration checks).

Table 1 lists QC checks often included in QAPPs. The need for the specific check depends on the project objectives.

Table 1. Project Quality Control Checks

QC Check	Information Provided
Blanks	
field blank	transport and field handling bias
reagent blank	contaminated reagent
rinsate blank	contaminated equipment
method blank	response of entire laboratory analytical system
Spikes	
matrix spike	analytical (preparation + analysis) bias
matrix spike replicate	analytical bias and precision
analysis matrix spike	instrumental bias
surrogate spike	analytical bias
Calibration Check Samples	
zero check	calibration drift and memory effects
span check	calibration drift and memory effects
mid-range check	calibration drift and memory effects
Replicates, splits, etc.	
collocated samples	sampling + measurement precision
field replicates	precision of all steps after acquisition
field splits	shipping + interlaboratory precision
laboratory splits	interlaboratory precision
laboratory replicates	analytical precision
analysis replicates	instrument precision

Many QC checks result in measurement data that are used to compute statistical indicators of data quality. For example, a series of dilute solutions may be measured repeatedly to produce an estimate of the instrument detection limit. The formulas for calculating such Data Quality Indicators (DQIs) should be provided or referenced in the text. This element should also prescribe any limits that define acceptable data quality for these indicators (see also Appendix D, “Data Quality Indicators”). A QC checklist should be used to discuss the relation of QC to the overall project objectives with respect to:

- the frequency and point in the measurement process in which the check sample is introduced,
- the traceability of the standards,
- the matrix of the check sample,
- the level or concentration of the analyte of interest,
- the actions to be taken if a QC check identifies a failed or changed measurement system,
- the formulas for estimating DQIs, and
- the procedures for documenting QC results, including control charts.

Finally, this element should describe how the QC check data will be used to determine that measurement performance is acceptable. This step can be accomplished by establishing QC "warning" and "control" limits for the statistical data generated by the QC checks (see standard QC textbooks or refer to EPA QA/G-5T for operational details).

Depending on the breadth of the potential audience for reviewing and implementing the QAPP, it may be advantageous to separate the field QC from the laboratory QC requirements.

B6 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

Describe how inspections and acceptance testing of environmental sampling and measurement systems and their components will be performed and documented.

Identify and discuss the procedure by which final acceptance will be performed by independent personnel and/or by the EPA Project Officer.

Describe how deficiencies are to be resolved and when re-inspection will be performed.

Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

B6.1 Purpose/Background

The purpose of this element of the QAPP is to discuss the procedures used to verify that all instruments and equipment are maintained in sound operating condition and are capable of operating at acceptable performance levels.

B6.2 Testing, Inspection, and Maintenance

The procedures described should (1) reflect consideration of the possible effect of equipment failure on overall data quality, including timely delivery of project results; (2) address any relevant site-specific effects (e.g., environmental conditions); and (3) include procedures for assessing the equipment status. This element should address the scheduling of routine calibration and maintenance activities, the steps that will be taken to minimize instrument downtime, and the prescribed corrective action procedures for addressing unacceptable inspection or assessment results. This element should also include periodic maintenance procedures and describe the availability of spare parts and how an inventory of these parts is monitored and maintained. The reader should be supplied with sufficient information to review the adequacy of the instrument/equipment management program. Appending SOPs containing this information to the QAPP and referencing the SOPs in the text are acceptable.

Inspection and testing procedures may employ reference materials, such as the National Institute of Standards and Technology's (NIST's) Standard Reference Materials (SRMs), as well as QC standards or an equipment certification program. The accuracy of calibration standards is important because all data will be measured in reference to the standard used. The types of standards or special programs should be noted in this element, including the inspection and acceptance testing criteria for all components. The acceptance limits for verifying the accuracy of all working standards against primary grade standards should also be provided.

B7 INSTRUMENT CALIBRATION AND FREQUENCY

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain performance within specified limits.

Identify the certified equipment and/or standards used for calibration. Describe or reference how calibration will be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

B7.1 Purpose/Background

This element of the QAPP concerns the calibration procedures that will be used for instrumental analytical methods and other measurement methods that are used in environmental measurements. It is necessary to distinguish between defining calibration as the checking of physical measurements against accepted standards and as determining the relationship (function) of the response versus the concentration. The American Chemical Society (ACS) limits the definition of the term *calibration* to the checking of physical measurements against accepted standards, and uses the term *standardization* to describe the determination of the response function.

B7.2 Identify the Instrumentation Requiring Calibration

The QAPP should identify any equipment or instrumentation that requires calibration to maintain acceptable performance. While the primary focus of this element is on instruments of the measurement system (sampling and measurement equipment), all methods require standardization to determine the relationship between response and concentration.

B7.3 Document the Calibration Method that Will Be Used for Each Instrument

The QAPP must describe the calibration method for each instrument in enough detail for another researcher to duplicate the calibration method. It may reference external documents such as EPA-designated calibration procedures or SOPs providing that these documents can be easily obtained. Nonstandard calibration methods or modified standard calibration methods should be fully documented and justified.

Some instrumentation may be calibrated against other instrumentation or apparatus (e.g., NIST thermometer), while other instruments are calibrated using standard materials traceable to national reference standards. QAPP documentation for calibration apparatus and calibration standards are addressed in B7.4 and B7.5.

Calibrations normally involve challenging the measurement system or a component of the measurement system at a number of different levels over its operating range. The calibration may cover a narrower range if accuracy in that range is critical, given the end use of the data. Single-point calibrations are of limited use, and two-point calibrations do not provide information on nonlinearity. If single- or two-point calibrations are used for critical measurements, the potential shortcomings should be carefully considered and discussed in the QAPP. Most EPA-approved analytical methods require multipoint (three or more) calibrations that include zeros, or blanks, and higher levels so that unknowns fall within the calibration range and are bracketed by calibration points. The number of calibration points, the calibration range, and any replication (repeated measures at each level) should be given in the QAPP.

The QAPP should describe how calibration data will be analyzed. The use of statistical QC techniques to process data across multiple calibrations to detect gradual degradations in the measurement system should be described. The QAPP should describe any corrective action that will be taken if calibration (or calibration check) data fail to meet the acceptance criteria, including recalibration. References to appended SOPs containing the calibration procedures are an acceptable alternative to describing the calibration procedures within the text of the QAPP.

B7.4 Document the Calibration Apparatus

Some instruments are calibrated using calibration apparatus rather than calibration standards. For example, an ozone generator is part of a system used to calibrate continuous ozone monitors. Commercially available calibration apparatus should be listed together with the make (the manufacturer's name), the model number, and the specific variable control settings that will be used during the calibrations. A calibration apparatus that is not commercially available should be described in enough detail for another researcher to duplicate the apparatus and follow the calibration procedure.

B7.5 Document the Calibration Standards

Most measurement systems are calibrated by processing materials that are of known and stable composition. References describing these calibration standards should be included in the QAPP. Calibration standards are normally traceable to national reference standards, and the traceability protocol should be discussed. If the standards are not traceable, the QAPP must include a detailed description of how the standards will be prepared. Any method used to verify the certified value of the standard independently should be described.

B7.6 Document Calibration Frequency

The QAPP must describe how often each measurement method will be calibrated. It is desirable that the calibration frequency be related to any known temporal variability (i.e., drift) of the measurement system. The calibration procedure may involve less-frequent comprehensive calibrations and more-frequent simple drift checks. The location of the record of calibration frequency and maintenance should be referenced.

B7.7 References

American Chemical Society. 1980. "Calibration." *Analytical Chemistry*, Vol. 52, pps. 2,242-2,249.

Dieck, R.H. 1992. *Measurement Uncertainty Methods and Applications.* Research Triangle Park, NC: Instrument Society of America.

Dux, J.P. 1986. *Handbook of Quality Assurance for the Analytical Chemistry Laboratory.* New York: Van Nostrand Reinhold.

ILAC Task Force E. 1984. *Guidelines for the Determination of Recalibration Intervals of Testing Equipment Used in Testing Laboratories.* International Organization for Legal Metrology (OIML). International Document No. 10. 11 Rue Twigot, Paris 95009, France.

Ku, H.H., ed. 1969. *Precision Measurement and Calibration. Selected NBS Papers on Statistical Concepts and Procedures.* Special Publication 300. Vol. 1. Gaithersburg, MD: National Bureau of Standards.

Liggett, W. 1986. "Tests of the Recalibration Period of a Drifting Instrument." In *Oceans '86 Conference Record.* Vol. 3. Monitoring Strategies Symposium. The Institute of Electrical and Electronics Engineers, Inc., Service Center. Piscataway, NJ.

Pontius, P.E. 1974. *Notes on the Fundamentals of Measurement as a Production Process.* Publication No. NBSIR 74-545. Gaithersburg, MD: National Bureau of Standards.

Taylor, J.T. 1987. *Quality Assurance of Chemical Measurements.* Boca Raton, FL: Lewis Publishers, Inc.

B8 INSPECTION/ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES

Describe how and by whom supplies and consumables shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

B8.1 Purpose

The purpose of this element is to establish and document a system for inspecting and accepting all supplies and consumables that may directly or indirectly affect the quality of the project or task. If these requirements have been included under another section, it is sufficient to provide a reference.

B8.2 Identification of Critical Supplies and Consumables

Clearly identify and document all supplies and consumables that may directly or indirectly affect the quality of the project or task. See Figures 9 and 10 for example documentation of inspection/acceptance testing requirements. Typical examples include sample bottles, calibration gases, reagents, hoses, materials for decontamination activities, deionized water, and potable water.

For each item identified, document the inspection or acceptance testing requirements or specifications (e.g., concentration, purity, cell viability, activity, or source of procurement) in addition to any requirements for certificates of purity or analysis.

B8.3 Establishing Acceptance Criteria

Acceptance criteria must be consistent with overall project technical and quality criteria (e.g., concentration must be within ± 2.5%, cell viability must be >90%). If special requirements are needed for particular supplies or consumables, a clear agreement should be established with the supplier, including the methods used for evaluation and the provisions for settling disparities.

B8.4 Inspection or Acceptance Testing Requirements and Procedures

Inspections or acceptance testing should be documented, including procedures to be followed, individuals responsible, and frequency of evaluation. In addition, handling and storage conditions for supplies and consumables should be documented.

B8.5 Tracking and Quality Verification of Supplies and Consumables

Procedures should be established to ensure that inspections or acceptance testing of supplies and consumables are adequately documented by permanent, dated, and signed records or logs that uniquely identify the critical supplies or consumables, the date received, the date tested, the date to be retested (if applicable), and the expiration date. These records should be kept by the responsible individual(s) (see Figure 11 for an example log). In order to track supplies and consumables, labels with the information on receipt and testing should be used.

These or similar procedures should be established to enable project personnel to (1) verify, prior to use, that critical supplies and consumables meet specified project or task quality objectives; and (2) ensure that supplies and consumables that have not been tested, have expired, or do not meet acceptance criteria are not used for the project or task.

Unique identification no. (if not clearly shown)______________________
Date received____
Date opened____
Date tested (if performed)_______________________________________
Date to be retested (if applicable)_________________________________
Expiration date____

Figure 9. Example of a Record for Consumables

Critical Supplies and Consumables	Inspection/ Acceptance Testing Requirements	Acceptance Criteria	Testing Method	Frequency	Responsible Individual	Handling/Storage Conditions

Figure 10. Example of Inspection/Acceptance Testing Requirements

Critical Supplies and Consumable (Type, ID No.)	Date Received	Meets Inspection/ Acceptance Criteria (Y/N, Include Date)	Requires Retesting (Y/N, If Yes, Include Date)	Expiration Date	Comments	Initials/Date

Figure 11. Example of a Log for Tracking Supplies and Consumables

B9 DATA ACQUISITION REQUIREMENTS (NON-DIRECT MEASUREMENTS)

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer databases, programs, literature files, and historical databases.

Define the acceptance criteria for the use of such data in the project and discuss any limitations on the use of the data resulting from uncertainty in its quality.

Document the rationale for the original collection of data and indicate its relevance to this project.

B9.1 Purpose/Background

This element of the QAPP should clearly identify the intended sources of previously collected data and other information that will be used in this project. Information that is non-representative and possibly biased and is used uncritically may lead to decision errors. The care and skepticism applied to the generation of new data are also appropriate to the use of previously compiled data (for example, data sources such as handbooks and computerized databases).

B9.2 Acquisition of Non-Direct Measurement Data

This element's criteria should be developed to support the objectives of element A7. Acceptance criteria for each collection of data being considered for use in this project should be explicitly stated, especially with respect to:

- **Representativeness.** Were the data collected from a population that is sufficiently similar to the population of interest and the population boundaries? How will potentially confounding effects (for example, season, time of day, and cell type) be addressed so that these effects do not unduly alter the summary information?

- **Bias.** Are there characteristics of the data set that would shift the conclusions. For example, has bias in analysis results been documented? Is there sufficient information to estimate and correct bias?

- **Precision.** How is the spread in the results estimated? Does the estimate of variability indicate that it is sufficiently small to meet the objectives of this project as stated in element A7? See also Appendix D.

- **Qualifiers.** Are the data evaluated in a manner that permits logical decisions on whether or not the data are applicable to the current project? Is the system of qualifying or flagging data adequately documented to allow the combination of data sets?

- **Summarization.** Is the data summarization process clear and sufficiently consistent with the goals of this project? (See element D2 for further discussion.) Ideally, observations and transformation equations are available so that their assumptions can be evaluated against the objectives of the current project.

This element should also include a discussion on limitations on the use of the data and the nature of the uncertainty of the data.

B10 DATA MANAGEMENT

Describe the project data management scheme, tracing the path of the data from their generation in the field or laboratory to their final use or storage. Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media.

Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures to process, compile, and analyze the data, including any required computer hardware and software. Address any specific performance requirements and describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required.

Describe the process for assuring that applicable Agency information resource management requirements and locational data requirements are satisfied. If other Agency data management requirements are applicable, discuss how these requirements are addressed.

B10.1 Purpose/Background

This element should present an overview of all mathematical operations and analyses performed on raw ("as-collected") data to change their form of expression, location, quantity, or dimensionality. These operations include data recording, validation, transformation, transmittal, reduction, analysis, management, storage, and retrieval. A diagram that illustrates the source(s) of the data, the processing steps, the intermediate and final data files, and the reports produced may be helpful, particularly when there are multiple data sources and data files. When appropriate, the data values should be subjected to the same chain-of-custody requirements as outlined in element B3. Appendix G has further details.

B10.2 Data Recording

Any internal checks (including verification and validation checks) that will be used to ensure data quality during data encoding in the data entry process should be identified together with the mechanism for detailing and correcting recording errors. Examples of data entry forms and checklists should be included.

B10.3 Data Validation

The details of the process of data validation and prespecified criteria should be documented in this element of the QAPP. This element should address how the method, instrument, or system performs the function it is intended to consistently, reliably, and accurately in generating the data. Part D of this document addresses the overall project data validation, which is performed after the project has been completed.

B10.4 Data Transformation

Data transformation is the conversion of individual data point values into related values or possibly symbols using conversion formulas (e.g., units conversion or logarithmic conversion) or a system for replacement. The transformations can be reversible (e.g., as in the conversion of data points using a formulas) or irreversible (e.g., when a symbol replaces actual values and the value is lost). The procedures for all data transformations should be described and recorded in this element. The procedure for converting calibration readings into an equation that will be applied to measurement readings should be documented in the QAPP. Transformation and aberration of data for statistical analysis should be outlined in element D3, "Reconciliation with Data Quality Objectives."

B10.5 Data Transmittal

Data transmittal occurs when data are transferred from one person or location to another or when data are copied from one form to another. Some examples of data transmittal are copying raw data from a notebook onto a data entry form for keying into a computer file and electronic transfer of data over a telephone or computer network. The QAPP should describe each data transfer step and the procedures that will be used to characterize data transmittal error rates and to minimize information loss in the transmittal.

B10.6 Data Reduction

Data reduction includes all processes that change the number of data items. This process is distinct from data transformation in that it entails an irreversible reduction in the size of the data set and an associated loss of detail. For manual calculations, the QAPP should include an example in which typical raw data are reduced. For automated data processing, the QAPP should clearly indicate how the raw data are to be reduced with a well-defined audit trail, and reference to the specific software documentation should be provided.

B10.7 Data Analysis

Data analysis sometimes involves comparing suitably reduced data with a conceptual model (e.g., a dispersion model or an infectivity model). It frequently includes computation of summary statistics, standard errors, confidence intervals, tests of hypotheses relative to model parameters, and goodness-of-fit tests. This element should briefly outline the proposed methodology for data analysis and a more detailed discussion should be included in the final report.

B10.8 Data Tracking

Data management includes tracking the status of data as they are collected, transmitted, and processed. The QAPP should describe the established procedures for tracking the flow of data through the data processing system.

B10.9 Data Storage and Retrieval

The QAPP should discuss data storage and retrieval including security and time of retention, and it should document the complete control system. The QAPP should also discuss the performance requirements of the data processing system, including provisions for the batch processing schedule and the data storage facilities.

C ASSESSMENT/OVERSIGHT

C1 ASSESSMENTS AND RESPONSE ACTIONS

Identify the number, frequency, and type of assessment activities needed for this project.

List and describe the assessments to be used in the project. Discuss the information expected and the success criteria for each assessment proposed. List the approximate schedule of activities, identify potential organizations and participants. Describe how and to whom the results of the assessments shall be reported.

Define the scope of authority of the assessors, including stop work orders. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act and provide an approximate schedule for the assessments to be performed.

Discuss how response actions to non-conforming conditions shall be addressed and by whom. Identify who is responsible for implementing the response action and describe how response actions shall be verified and documented.

C1.1 Purpose/Background

During the planning process, many options for sampling design (see EPA QA/G-5S, *Guidance on Sampling Design to Support QAPPs*), sample handling, sample cleanup and analysis, and data reduction are evaluated and chosen for the project. In order to ensure that the data collection is conducted as planned, a process of evaluation and validation is necessary. This element of the QAPP describes the internal and external checks necessary to ensure that:

- all elements of the QAPP are correctly implemented as prescribed,
- the quality of the data generated by implementation of the QAPP is adequate, and
- corrective actions, when needed, are implemented in a timely manner and their effectiveness is confirmed.

Although any external assessments that are planned should be described in the QAPP, the most important part of this element is documenting all planned internal assessments. Generally, internal assessments are initiated or performed by the internal QA Officer so the activities described in this element should be related to the responsibilities of the QA Officer as discussed in Section A4.

C1.2 Assessment Activities and Project Planning

The following is a description of various types of assessment activities available to managers in evaluating the effectiveness of environmental program implementation.

C1.2.1 <u>Assessment of the Subsidiary Organizations</u>

A. *Management Systems Review (MSR).* A form of management assessment, this process is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. The

MSR is used to ensure that sufficient management controls are in place and carried out by the organization to adequately plan, implement, and assess the results of the project. See the *Guidance for the Management Systems Review Process* (EPA QA/G-3).

B. *Readiness reviews.* A readiness review is a technical check to determine if all components of the project are in place so that work can commence on a specific phase.

C1.2.2 Assessment of Project Activities

A. *Surveillance.* Surveillance is the continual or frequent monitoring of the status of a project and the analysis of records to ensure that specified requirements are being fulfilled.

B. *Technical Systems Audit (TSA).* A TSA is a thorough and systematic onsite qualitative audit, where facilities, equipment, personnel, training, procedures, and record keeping are examined for conformance to the QAPP. The TSA is a powerful audit tool with broad coverage that may reveal weaknesses in the management structure, policy, practices, or procedures. The TSA is ideally conducted after work has commenced, but before it has progressed very far, thus giving opportunity for corrective action.

C. *Performance Evaluation (PE).* A PE is a type of audit in which the quantitative data generated by the measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory. "Blind" PE samples are those whose identity is unknown to those operating the measurement system. Blind PEs often produce better performance assessments because they are handled routinely and are not given the special treatment that undisguised PEs sometimes receive. The QAPP should list the PEs that are planned, identifying:

- the constituents to be measured,
- the target concentration ranges,
- the timing/schedule for PE sample analysis, and
- the aspect of measurement quality to be assessed (e.g., bias, precision, and detection limit).

A number of EPA regulations and EPA-sanctioned methods require the successful accomplishment of PEs before the results of the test can be considered valid. PE materials are now available from commercial sources and a number of EPA Program Offices coordinate various interlaboratory studies and laboratory proficiency programs. Participation in these or in the National Voluntary Laboratory Accreditation Program (NVLAP, run by NIST) should be mentioned in the QAPP.

D. *Audit of Data Quality (ADQ).* An ADQ reveals how the data were handled, what judgments were made, and whether uncorrected mistakes were made. Performed prior to producing a project's final report, ADQs can often identify the means to correct systematic data reduction errors.

E. *Peer review.* Peer review is not a TSA, nor strictly an internal QA function, as it may encompass non-QA aspects of a project and is primarily designed for scientific review. Whether a planning team chooses ADQs or peer reviews depends upon the nature of the project, the intended use of the data, the policies established by the sponsor of the project, and overall the conformance to the Program Office or Region's peer-review policies and procedures. Reviewers are chosen who have technical expertise comparable to the project's performers but who are independent of the project. ADQs and peer reviews ensure that the project activities:

- were technically adequate,
- were competently performed,
- were properly documented,
- satisfied established technical requirements, and
- satisfied established QA requirements.

In addition, peer reviews assess the assumptions, calculations, extrapolations, alternative interpretations, methods, acceptance criteria, and conclusions documented in the project's report. Any plans for peer review should conform with the Agency's peer-review policy and guidance. The names, titles, and positions of the peer reviewers should be included in the final QAPP, as should their report findings, the QAPP authors' documented responses to their findings, and reference to where responses to peer-review comments may be located, if necessary.

F. *Data Quality Assessment (DQA).* DQA involves the application of statistical tools to determine whether the data meet the assumptions that the DQOs and data collection design were developed under and whether the total error in the data is tolerable. *Guidance for the Data Quality Assessment Process* (EPA QA/G-9) provides nonmandatory guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations.

C1.3 Documentation of Assessments

The following material describes what should be documented in a QAPP after consideration of the above issues and types of assessments.

C1.3.1 Number, Frequency, and Types of Assessments

Depending upon the nature of the project, there may be more than one assessment. A schedule of the number, frequencies, and types of assessments required should be given.

C1.3.2 Assessment Personnel

The QAPP should specify the individuals, or at least the specific organizational units, who will perform the assessments. Internal audits are usually performed by personnel who work for the organization performing the project work but who are organizationally independent of the management of the project. External audits are performed by personnel of organizations not connected with the project but who are technically qualified and who understand the QA requirements of the project.

C1.3.3 Schedule of Assessment Activities

A schedule of audit activities, together with relevant criteria for assessment, should be given to the extent that it is known in advance of project activities.

C1.3.4 Reporting and Resolution of Issues

Audits, peer reviews, and other assessments often reveal findings of practice or procedure that do not conform to the written QAPP. Because these issues must be addressed in a timely manner, the protocol for resolving them should be given here together with the proposed actions to ensure that the corrective actions were performed effectively. The person to whom the concerns should be addressed, the decision making hierarchy, the schedule and format for oral and written reports, and the responsibility for corrective action should all be discussed in this element. It also should explicitly define the unsatisfactory conditions upon which the assessors are authorized to act and list the project personnel who should receive assessment reports.

C2 REPORTS TO MANAGEMENT

Identify the frequency and distribution of reports issued to inform management of the status of the project; results of performance evaluations and systems audits; results of periodic data quality assessments; and significant quality assurance problems and recommended solutions.

Identify the preparer and the recipients of the reports, and the specific actions management is expected to take as a result of the reports.

C2.1 Purpose/Background

Effective communication between all personnel is an integral part of a quality system. Planned reports provide a structure for apprising management of the project schedule, the deviations from approved QA and test plans, the impact of these deviations on data quality, and the potential uncertainties in decisions based on the data. Verbal communication on deviations from QA plans should be noted in summary form in element D1 of the QAPP.

C2.2 Frequency, Content, and Distribution of Reports

The QAPP should indicate the frequency, content, and distribution of the reports so that management may anticipate events and move to ameliorate potentially adverse results. An important benefit of the status reports is the opportunity to alert the management of data quality problems, propose viable solutions, and procure additional resources. If program assessment (including the evaluation of the technical systems, the measurement of performance, and the assessment of data) is not conducted on a continual basis, the integrity of the data generated in the program may not meet the quality requirements. These audit reports, submitted in a timely manner, will provide an opportunity to implement corrective actions when most appropriate.

C2.3 Identify Responsible Organizations

It is important that the QAPP identify the personnel responsible for preparing the reports, evaluating their impact, and implementing follow-up actions. It is necessary to understand how any changes made in one area or procedure may affect another part of the project. Furthermore, the documentation for all changes should be maintained and included in the reports to management. At the end of a project, a report documenting the Data Quality Assessment findings to management should be prepared.

D DATA VALIDATION AND USABILITY

D1 DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

State the criteria used to review and validate data.
Provide examples of any forms or checklists to be used.
Identify any project-specific calculations required.

D1.1 Purpose/Background

The purpose of this element is to state the criteria for deciding the degree to which each data item has met its quality specifications as described in Group B. Investigators should estimate the potential effect that each deviation from a QAPP may have on the usability of the associated data item, its contribution to the quality of the reduced and analyzed data, and its effect on the decision.

The process of data verification requires confirmation by examination or provision of objective evidence that the requirements of these specified QC acceptance criteria are met. In design and development, verification concerns the process of examining the result of a given activity to determine conformance to the stated requirements for that activity. For example, have the data been collected according to a specified method and have the collected data been faithfully recorded and transmitted? Do the data fulfill specified data format and metadata requirements. The process of data verification effectively ensures the accuracy of data using validated methods and protocols and is often based on comparison with reference standards.

The process of data validation requires confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs. For example, have the data and assessment methodology passed a peer review to evaluate the adequacy of their accuracy and precision in assessing progress towards meeting the specific commitment articulated in the objective or subobjective. The method validation process effectively develops the QC acceptance criteria or specific performance criteria.

Each of the following areas of discussion should be included in the QAPP elements. The discussion applies to situations in which a sample is separated from its native environment and transported to a laboratory for analysis and data generation. However, these principles can be adapted to other situations (for example, *in-situ* analysis or laboratory research).

D1.2 Sampling Design

How closely a measurement represents the actual environment at a given time and location is a complex issue that is considered during development of element B1. See *Guidance on Sampling Designs to Support QAPPs (*EPA QA/G-5S). Acceptable tolerances for each critical sample coordinate and the action to be taken if the tolerances are exceeded should be specified in element B1.

Each sample should be checked for conformity to the specifications, including type and location (spatial and temporal). By noting the deviations in sufficient detail, subsequent data users will be able to determine the data's usability under scenarios different from those included in project planning. The strength of conclusions that can be drawn from data (see *Guidance Document for Data Quality Assessment*, EPA QA/G-9) has a direct connection to the sampling design and deviations from that design. Where auxiliary variables are included in the overall data collection effort (for example, microbiological nutrient characteristics or process conditions), they should be included in this evaluation.

D1.3 Sample Collection Procedures

Details of how a sample is separated from its native time/space location are important for properly interpreting the measurement results. Element B2 provides these details, which include sampling and ancillary equipment and procedures (including equipment decontamination). Acceptable departures (for example, alternate equipment) from the QAPP, and the action to be taken if the requirements cannot be satisfied, should be specified for each critical aspect. Validation activities should note potentially unacceptable departures from the QAPP. Comments from field surveillance on deviations from written sampling plans also should be noted.

D1.4 Sample Handling

Details of how a sample is physically treated and handled during relocation from its original site to the actual measurement site are extremely important. Correct interpretation of the subsequent measurement results requires that deviations from element B3 of the QAPP and the actions taken to minimize or control the changes, be detailed. Data collection activities should indicate events that occur during sample handling that may affect the integrity of the samples.

At a minimum, investigators should evaluate the sample containers and the preservation methods used and ensure that they are appropriate to the nature of the sample and the type of data generated from the sample. Checks on the identity of the sample (e.g., proper labeling and chain-of-custody records) as well as proper physical/chemical storage conditions (e.g., chain-of-custody and storage records) should be made to ensure that the sample continues to be representative of its native environment as it moves through the analytical process.

D1.5 Analytical Procedures

Each sample should be verified to ensure that the procedures used to generate the data (as identified in element B4 of the QAPP) were implemented as specified. Acceptance criteria should be developed for important components of the procedures, along with suitable codes for characterizing each sample's deviation from the procedure. Data validation activities should determine how seriously a sample deviated beyond the acceptable limit so that the potential effects of the deviation can be evaluated during DQA.

D1.6 Quality Control

Element B5 of the QAPP specifies the QC checks that are to be performed during sample collection, handling, and analysis. These include analyses of check standards, blanks, spikes, and replicates, which provide indications of the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action (and changes) should be specified. Data validation should document the corrective actions that were taken, which samples were affected, and the potential effect of the actions on the validity of the data.

D1.7 Calibration

Element B7 addresses the calibration of instruments and equipment and the information that should be presented to ensure that the calibrations:

- were performed within an acceptable time prior to generation of measurement data;
- were performed in the proper sequence;
- included the proper number of calibration points;
- were performed using standards that “bracketed” the range of reported measurement results (otherwise, results falling outside the calibration range are flagged as such); and
- had acceptable linearity checks and other checks to ensure that the measurement system was stable when the calibration was performed.

When calibration problems are identified, any data produced between the suspect calibration event and any subsequent recalibration should be flagged to alert data users.

D1.8 Data Reduction and Processing

Checks on data integrity evaluate the accuracy of “raw” data and include the comparison of important events and the duplicate rekeying of data to identify data entry errors.

Data reduction is an irreversible process that involves a loss of detail in the data and may involve averaging across time (for example, hourly or daily averages) or space (for example, compositing results from samples thought to be physically equivalent). Since this summarizing process produces few values to represent a group of many data points, its validity should be well-documented in the QAPP. Potential data anomalies can be investigated by simple statistical analyses (see *Guidance for Data Quality Assessment*, EPA QA/G-9).

The information generation step involves the synthesis of the results of previous operations and the construction of tables and charts suitable for use in reports. How information generation is checked, the requirements for the outcome, and how deviations from the requirements will be treated, should be addressed in this element.

D2 VALIDATION AND VERIFICATION METHODS

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task.

Discuss how issues shall be resolved and identify the authorities for resolving such issues.

Describe how the results are conveyed to the data users.

Precisely define and interpret how validation issues differ from verification issues for this project.

D2.1 Purpose/Background

The purpose of this element is to describe, in detail, the process for validating (determining if data satisfy QAPP-defined user requirements) and verifying (ensuring that conclusions can be correctly drawn) project data. The amount of data validated is directly related to the DQOs developed for the project. The percentage validated for the specific project together with its rationale should be outlined or referenced. The QAPP should have a clear definition of what is implied by "verification" and "validation."

D2.2 Describe the Process for Validating and Verifying Data

The individuals responsible for data validation together with the lines of authority should be shown on an organizational chart and may be indicated in the chart in element A7. The chart should indicate who is responsible for each activity of the overall validation and verification processes.

The data to be validated should be compared to "actual" events using the criteria documented in the QAPP. The data validation procedure for all environmental measurements should be documented in the SOPs for specific data validation. Verification and validation issues are discussed at length in *Guidance on Environmental Verification and Validation,* (EPA QA/G-8).

D3 RECONCILIATION WITH DATA QUALITY OBJECTIVES

Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision maker.

Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection.

Describe how issues will be resolved and discuss how limitations on the use of the data will be reported to decision makers.

D3.1 Purpose/Background

The purpose of element D3 is to outline and specify, if possible, the acceptable methods for evaluating the results obtained from the project. This element includes scientific and statistical evaluations of data to determine if the data are of the right type, quantity, and quality to support their intended use.

D3.2 Reconciling Results with DQOs

The DQA process has been developed for cases where formal DQOs have been established. *Guidance for Data Quality Assessment* (EPA QA/G-9) focuses on evaluating data for fitness in decision making and also provides many graphical and statistical tools.

DQA is a key part of the assessment phase of the data life cycle, as shown in Figure 1. As the part of the assessment phase that follows data validation and verification, DQA determines how well the validated data can support their intended use. If an approach other than DQA has been selected, an outline of the proposed activities should be included.

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APPENDIX A

Bureau of Environmental Services
Office of Quality Assurance

Quality Assurance Project Plan (QAPP) Checklist

Study Title:____
Date Received:__________________**Date Review Completed:**____________________
SQAMO or QA Officer Signature____

The QA Project Plan must address the following groups of elements:

A. Project Management- This group of QAPP elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc.

A1	____	Title and Approval Sheet (Project Officer Must Sign and Date)
A2	____	Table of Contents
A3	____	Distribution List (QAPP and Final Reports)
A4	____	Project/Task Organization
A5	____	Problem Definition/Background
A6	____	Project/Task Description
A7	____	Data Quality Objectives and Criteria for Data Measurement
A8	____	Special Training Requirements/Certifications (If Required)
A9	____	Documentation and Records

B. Measurement/Data Acquisition- This group of QAPP elements covers all aspects of measurement system design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and properly documented.

B1	____	Sampling Process Design(Experimental Design)
B2	____	Sampling Methods Requirements
B3	____	Sample Handling and Chain of Custody
B4	____	Analytical Methods Requirements(Cite Approved Methods Used)
B5	____	Quality Control Requirements
B6	____	Instrument/Equipment Selection, Preventative and Remedial Maintenance
B7	____	Instrument Calibration Procedures
B8	____	Inspection/Acceptance Requirements for Supplies and Consumables
B9	____	Data Acquisition Requirements(Non- direct Measurements)
B10	____	Data Management (Record- Keeping and Data Storage)

C. Assessment/Oversight- This group of QAPP elements addresses the activities for assessing the effectiveness of the associated QA/QC.

C1 ____ Assessment Activities and Corrective Action
C2 ____ Reports of Performance Evaluations, System Audits, Data Assessments

D. Data Validation and Usability- This group of QAPP elements covers the activities that occur after data collection and ensure specified project criteria are achieved.

D1 ____ Data Review, Validation, and Verification
D2 ____ Documentation, Data Reduction and Reporting
D3 ____ Interim/ Final Reports and Limitations on Data Use

Documentation, such as the Work Plan, Standard Operating Procedures(SOPs), etc., may be referenced in response to a particular required QAPP element to reduce the size of the QAPP and the time required for preparation and review. All referenced documents must be attached to the QAPP. Such references must be kept current by the submitter.

Comments:____
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South Carolina Department of Health and Environmental Control

APPENDIX A (Continued)

Bureau of Environmental Services
Office of Quality Assurance

PQAP Checklist

Study Title: ____

Date Received:______________Date Review Completed:_______________

SQAMO or QA Officer Signature__________________________________

The PQAP shall include or address:

___ a project description, including the purpose of the work, data collection activities to be performed, and how the environmental data will be used;

___ a statement of the project objectives, expected level of confidence in data, and criteria for successful completion;

___ a description of the sampling and analytical design, including identifying critical and non critical aspects, sampling and analytical methods to be used, calibration requirements for instruments, and performance criteria;

___ a description of the handling and custody of samples, including sample identification, preservation, transportation, storage, and disposal;

___ a listing of the proposed start and ending dates for the project and deliverables, signature of project manager and date;

___ a listing of the key project staff and their roles and responsibilities;

___ a description of how quality will be assured during the project, including the use of performance evaluations, assessments, procedures for data validation and verification, corrective actions, and QA/QC activities performed

SCDHEC PQAP Directive, August 1999, EPA QA/R5

APPENDIX B

GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS

Acceptance criteria — Specified limits placed on characteristics of an item, process, or service defined in requirements documents. (ASQC Definitions)

Accuracy — A measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; the EPA recommends using the terms *"precision"* and *"bias"*, rather than "accuracy," to convey the information usually associated with accuracy. Refer to *Appendix D, Data Quality Indicators* for a more detailed definition.

Activity — An all-inclusive term describing a specific set of operations of related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that, in total, result in a product or service.

Assessment — The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation (PE), management systems review (MSR), peer review, inspection, or surveillance.

Audit (quality) — A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Audit of Data Quality (ADQ) — A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Authenticate — The act of establishing an item as genuine, valid, or authoritative.

Bias — The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). Refer to *Appendix D, Data Quality Indicators,* for a more detailed definition.

Blank — A sample subjected to the usual analytical or measurement process to establish a zero baseline or background value. Sometimes used to adjust or correct routine analytical results. A sample that is intended to contain none of the analytes of interest. A blank is used to detect contamination during sample handling preparation and/or analysis.

Calibration — A comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

Calibration drift — The deviation in instrument response from a reference value over a period of time before recalibration.

Certification — The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody — An unbroken trail of accountability that ensures the physical security of samples, data, and records.

Characteristic — Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Check standard — A standard prepared independently of the calibration standards and analyzed exactly like the samples. Check standard results are used to estimate analytical precision and to indicate the presence of bias due to the calibration of the analytical system.

Collocated samples — Two or more portions collected at the same point in time and space so as to be considered identical. These samples are also known as field replicates and should be identified as such.

Comparability — A measure of the confidence with which one data set or method can be compared to another.

Completeness — A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. Refer to *Appendix D, Data Quality Indicators,* for a more detailed definition.

Confidence Interval — The numerical interval constructed around a point estimate of a population parameter, combined with a probability statement (the confidence coefficient) linking it to the population's true parameter value. If the same confidence interval construction technique and assumptions are used to calculate future intervals, they will include the unknown population parameter with the same specified probability.

Confidentiality procedure — A procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

Configuration — The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformance — An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

Consensus standard — A standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

Contractor — Any organization or individual contracting to furnish services or items or to perform work.

Corrective action — Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Data Quality Assessment (DQA) — The scientific and statistical evaluation of data to determine if data obtained from environmental operations are of the right type, quality, and quantity to support their intended use. The five steps of the DQA Process include: 1) reviewing the DQOs and sampling design, 2) conducting a preliminary data review, 3) selecting the statistical test, 4) verifying the assumptions of the statistical test, and 5) drawing conclusions from the data.

Data Quality Indicators (DQIs) — The quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy (bias is preferred), comparability, completeness, representativeness.

Data Quality Objectives (DQOs) — The qualitative and quantitative statements derived from the DQO Process that clarify study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives (DQO) Process — A systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. DQOs are the qualitative and quantitative outputs from the DQO Process.

Data reduction — The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

Data usability — The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Deficiency — An unauthorized deviation from acceptable procedures or practices, or a defect in an item.

Demonstrated capability — The capability to meet a procurement's technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

Design — The specifications, drawings, design criteria, and performance requirements. Also, the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Design change — Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design review — A documented evaluation by a team, including personnel such as the responsible designers, the client for whom the work or product is being designed, and a quality assurance (QA) representative but excluding the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Detection Limit (DL) — A measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. DLs are analyte- and matrix-specific and may be laboratory-dependent.

Distribution — 1) The appointment of an environmental contaminant at a point over time, over an area, or within a volume; 2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

Document control — The policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's requirements.

Duplicate samples — Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis. See also *collocated sample*.

Environmental conditions — The description of a physical medium (e.g., air, water, soil, sediment) or a biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental data — Any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

Environmental data operations — Any work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental monitoring — The process of measuring or collecting environmental data.

Environmental processes — Any manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

Environmental programs — An all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Environmental technology — An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from, or to prevent them from entering, the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it can also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Estimate — A characteristic from the sample from which inferences on parameters can be made.

Evidentiary records — Any records identified as part of litigation and subject to restricted access, custody, use, and disposal.

Expedited change — An abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

Field blank — A blank used to provide information about contaminants that may be introduced during sample collection, storage, and transport. A clean sample, carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.

Field (matrix) spike — A sample prepared at the sampling point (i.e., in the field) by adding a known mass of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency (the analytical bias).

Field split samples — Two or more representative portions taken from the same sample and submitted for analysis to different laboratories to estimate interlaboratory precision.

Financial assistance — The process by which funds are provided by one organization (usually governmental) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and governmental interagency agreements.

Finding — An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

Goodness-of-fit test — The application of the chi square distribution in comparing the frequency distribution of a statistic observed in a sample with the expected frequency distribution based on some theoretical model.

Grade — The category or rank given to entities having the same functional use but different requirements for quality.

Graded approach — The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results. (See also *Data Quality Objectives (DQO) Process.*)

Guidance — A suggested practice that is not mandatory, intended as an aid or example in complying with a standard or requirement.

Guideline — A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste — Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, "Identification and Listing of Hazardous Waste."

Holding time — The period of time a sample may be stored prior to its required analysis. While exceeding the holding time does not necessarily negate the veracity of analytical results, it causes the qualifying or "flagging" of any data not meeting all of the specified acceptance criteria.

Identification error — The misidentification of an analyte. In this error type, the contaminant of concern is unidentified and the measured concentration is incorrectly assigned to another contaminant.

Independent assessment — An assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection — The examination or measurement of an item or activity to verify conformance to specific requirements.

Internal standard — A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Laboratory split samples — Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the interlaboratory precision or variability and the data comparability.

Limit of quantitation — The minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Management — Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system — A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review (MSR) — The qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Matrix spike — A sample prepared by adding a known mass of a target analyte to a specified amount of matrix sample for which an independent estimate of the target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Mean (arithmetic) — The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

Mean squared error — A statistical term for variance added to the square of the bias.

Measurement and Testing Equipment (M&TE) — Tools, gauges, instruments, sampling devices, or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Memory effects error — The effect that a relatively high concentration sample has on the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument.

Method — A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method blank — A blank prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and quality control (QC) samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.

Mid-range check — A standard used to establish whether the middle of a measurement method's calibrated range is still within specifications.

Mixed waste — A hazardous waste material as defined by 40 CFR 261 Resource Conservation and Recovery Act (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

Must — When used in a sentence, a term denoting a requirement that has to be met.

Nonconformance — A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence — Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Observation — An assessment conclusion that identifies a condition (either positive or negative) that does not represent a significant impact on an item or activity. An observation may identify a condition that has not yet caused a degradation of quality.

Organization — A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Organization structure — The responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

Outlier — An extreme observation that is shown to have a low probability of belonging to a specified data population.

Parameter — A quantity, usually unknown, such as a mean or a standard deviation characterizing a population. Commonly misused for "variable," "characteristic," or "property."

Peer review — A documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. Conducted by qualified individuals (or an organization) who are independent of those who performed the work but collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. Peer reviews are conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. An in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) — A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Pollution prevention — An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge into the environment.

Precision — A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions expressed generally in terms of the standard deviation. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

Procedure — A specified way to perform an activity.

Process — A set of interrelated resources and activities that transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Project — An organized set of activities within a program.

Qualified data — Any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Qualified services — An indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

Quality — The totality of features and characteristics of a product or service that bears on its ability to meet the stated or implied needs and expectations of the user.

Quality Assurance (QA) — An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Program Description/Plan — See *quality management plan*.

Quality Assurance Project Plan (QAPP) — A formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into four classes: 1) Project Management, 2) Measurement/Data Acquisition, 3) Assessment/Oversight, and 4) Data Validation and Usability. Requirements for preparing QAPPs can be found in EPA QA/R-5.

Quality Control (QC) — The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring the results are of acceptable quality.

Quality control (QC) sample — An uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. Generally used to establish intralaboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

Quality improvement — A management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality management — That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) — A formal document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted.

Quality system — A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC).

Radioactive waste — Waste material containing, or contaminated by, radionuclides, subject to the requirements of the Atomic Energy Act.

Readiness review — A systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Record (quality) — A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Recovery — The act of determining whether or not the methodology measures all of the analyte contained in a sample. Refer to *Appendix D, Data Quality Indicators,* for a more detailed definition.

Remediation — The process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Repeatability — The degree of agreement between independent test results produced by the same analyst, using the same test method and equipment on random aliquots of the same sample within a short time period.

Reporting limit — The lowest concentration or amount of the target analyte required to be reported from a data collection project. Reporting limits are generally greater than detection limits and are usually not associated with a probability level.

Representativeness — A measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. See also *Appendix D, Data Quality Indicators.*

Reproducibility — The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Requirement — A formal statement of a need and the expected manner in which it is to be met.

Research (applied) — A process, the objective of which is to gain the knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Research (basic) — A process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

Research development/demonstration — The systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Round-robin study — A method validation study involving a predetermined number of laboratories or analysts, all analyzing the same sample(s) by the same method. In a round-robin study, all results are compared and used to develop summary statistics such as interlaboratory precision and method bias or recovery efficiency.

Ruggedness study — The carefully ordered testing of an analytical method while making slight variations in test conditions (as might be expected in routine use) to determine how such variations affect test results. If a variation affects the results significantly, the method restrictions are tightened to minimize this variability.

Scientific method — The principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

Self-assessment — The assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Sensitivity — the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

Service — The result generated by activities at the interface between the supplier and the customer, and the supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and/or field analysis, repair, and installation.

Shall — A term denoting a requirement that is mandatory whenever the criterion for conformance with the specification permits no deviation. This term does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Significant condition — Any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software life cycle — The period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirement phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Source reduction — Any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

Span check — A standard used to establish that a measurement method is not deviating from its calibrated range.

Specification — A document stating requirements and referring to or including drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

Spike — A substance that is added to an environmental sample to increase the concentration of target analytes by known amounts; used to assess measurement accuracy (spike recovery). Spike duplicates are used to assess measurement precision.

Split samples — Two or more representative portions taken from one sample in the field or in the laboratory and analyzed by different analysts or laboratories. Split samples are quality control (QC) samples that are used to assess analytical variability and comparability.

Standard deviation — A measure of the dispersion or imprecision of a sample or population distribution expressed as the positive square root of the variance and has the same unit of measurement as the mean.

Standard Operating Procedure (SOP) — A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier — Any individual or organization furnishing items or services or performing work according to a procurement document or a financial assistance agreement. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surrogate spike or analyte — A pure substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them to establish that the analytical meyhod has been performed properly.

Surveillance (quality) — Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Technical review — A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements have been satisfied.

Technical Systems Audit (TSA) — A thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

Traceability — The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

Trip blank — A clean sample of a matrix that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

Validation — Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs. See also *Appendix G, Data Management.*

Variance (statistical) — A measure or dispersion of a sample or population distribution.

Verification — Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

APPENDIX C

Example 1

<u>Quality Assurance Project Plan</u>:

> **"Urban Watershed Protection and Enhancement Through Stewardship and Education"**

Example 2

<u>Proposal Quality Assurance Plan</u>:

> **"Rawls Creek NPS Assessment & Community Education Project"**

APPENDIX C - EXAMPLE 1

QUALITY ASSURANCE PROJECT PLAN

PROJECT MANGEMENT

Project Title:
Urban Watershed Protection and Enhancement Through Stewardship and Education

Lead Organization:

Project Manager: Dr. William R. English
261 Lehotsky HALL, Clemson University, Clemson, SC
Phone: 864-656-4861, Fax: 864-656-06783304, e-mail:
renglsh@clemson.edu

Cooperating Organizations:
Clemson University Cooperative Extension Service – Greenville and Spartanburg Counties
University of South Carolina, Spartanburg
Hub City Writers Project
USDA-Natural Resources Conservation Service (NRCS)
Greenville and Spartanburg Soil and Water Conservation Districts

PROJECT LOCATION:
Lawsons Fork Creek in Spartanburg Co., Hydrologic Unit:03050105-180
and
Princess Creek, a tributary of the Enoree River in Greenville Co. Hydrologic Unit:3050108-010

		Date
Project Coordinator & QA Officer- William R. English PhD Dept. of Forest Resources, Clemson U.	Wm R. English	5/10/99
Project Field Manager - Sally Palmer, Dept. of Forest Resources, Clemson U.	M Sally Palmer	5/12/99
Project Advisor (Fecal Coliform Lab) Jack Turner, PhD Department of Biology USC Spartanburg	Jack H. Turner	5/18/99
SQAMO, SCDHEC		

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University of South Carolina, Spartanburg, Department of Biology

Hub City Writers Project

USDA-Natural Resources Conservation Service (NRCS)

Greenville and Spartanburg Soil and Water Conservation Districts

SC Department of Health and Environmental Control

Project Coordinator- William R. English

Project Field Manager-Sally Palmer

Project QA Officer- William R. English

EPA Project Manager

SQAMO, SCDHEC

Project /Task Organization

Project Coordinator- William R. English

Project Field Manager-Sally Palmer

Project QA Officer- William R. English

EPA Project Manager

SQAMO, SCDHEC

Problem Identification/Background

Despite efforts in water discharge regulations, SCDHEC monitoring data reminds us that we have been unable to protect the quality of rivers and streams without developing good stewardship of the land that drains into them. Because non-point source pollution is difficult to regulate and so greatly affects the quality of our surface and ground water, watershed education programs coupled with stewardship activities should be effective in protecting water quality. Implementation of stewardship/education programs will have greatest visibility and be most effective at sites showing the worst water quality.

Lawsons Fork Creek located in Spartanburg County and Princess Creek, located in Greenville County are targeted for our project efforts. Lawsons Fork Creek flows from an area of old mini-farms and new housing developments and industry near Inman, SC into a mix of more mini-farms, new housing, old and new industry and residential districts in Spartanburg, SC before joining with the Pacolet River. Two SCDHEC stations have evaluated the water quality of this creek. A monitoring station (B-221) is located off S-42-40 near Inman, SC and Station Bl-001 is located downstream of Spartanburg off S-42-108 just before Lawsons Fork Creek joins with the Pacolet River near Pacolet, SC. Lawsons Fork Creek is ranked as a number one priority area on the SCDNR 303(d) list. It is impaired for use in recreation (swimming) and for aquatic animal life. The principle causes for the number one priority ranking and nonsupport of use are the presence of fecal coliform bacteria beyond acceptable limits and lack of biotic integrity in the macroinvertebrate community.

Princess Creek drains the western edge of Greer, SC. The SCDHEC station B-192, located off Suber Mill Rd. on the outskirts of Greer indicated priority one/two ranking for impairment. Indicated impaired uses are for recreation (swimming) and for aquatic animal life. Nonsupport of use comes from the presence of fecal coliform bacteria and either Zinc or pH related problems that most likely affect biotic integrity.

The variety of land uses within each watershed and many different potential sources of water contaminants make the problems of these two creeks typical examples of what will be faced by communities throughout South Carolina as our population continues to grow. The characteristics of these two watersheds in rapidly expanding communities will form the basis for the deliverance of educational programs addressing a variety of water problems and the techniques used for the protection and enhancement of water quality.

Project/Task Description

1. Educate a group of concerned citizens on basic water quality monitoring techniques. And in so doing capture the excitement and attention of local communities (Role of Volunteer Water Quality Monitoring Programs in the Cooperative Extension Service, 1998). The monitoring groups will be instrumental in stewardship development, and most likely form the core of the stewardship group.

2. The volunteer monitoring groups will fine tune SCDHEC assessments by determining specific areas of concern (SAC) within each watershed (e.g. high fecal coliform counts below Human Society Facility).
3. The SACs will be used to target the efforts for development of educational programs, materials and confidential environmental assessments (e.g. Farm/Home-a-syst self assessment for pet care-providers)
4. Following the implementation of educational efforts and during the closing stages of the proposed grant period, volunteer monitors will re-evaluate the same sites that generated SACs to see if water quality has improved because of education efforts.

Each assessment will include sampling of temperature, pH, dissolved oxygen and nitrate nitrogen. At the same sites, macroinvertebrates and fecal coliform will be sampled and stream habitat assessment will be conducted.

Chemical analysis will be conducted on site with thermometers, dissolved oxygen meters. pH and nitrate nitrogen will be determined with Hach Co. water quality chemical kits.

Macroinvertebrates will be returned to lab or classroom for identification, documentation and preservation. Water samples for fecal coliform monitoring will also be returned to the lab for analysis.

Following each assessment all data will be entered into a computerized management system and analyzed. Reports of findings will be produced within three months of sample dates.

Data Quality Objectives for Measurement Data

Matrix	Parameter	Precision	Accuracy	MR
Water	pH	20%	0.5	3-10.5
Water	temperature	20%	0.20 C	-10-100 C
Water	dissolved oxygen	20%	0.3 mg/l	1-20 mg/l
Water	Nitrate	20%	0.03 mg/l	

Macroinvertebrate monitoring, and stream habitat assessment will be conducted according to the protocol established by the EPA for an Intensive Stream Biosurvy. Page 86 -123 in EPA Doc. EPA 841-B-97-003 "Volunteer Stream monitoring: A methods Manual". Fecal coliform monitoring will be conducted as directed in the same document and described in section 5.11, page 180-185.

Training Requirements/Certification

Student and citizen volunteers monitors will be provided a minimum of three hours training before actual monitoring begins. Classroom and field training will be taught by Clemson University and University of South Carolina, Spartanburg water quality faculty and staff.

Training will cover equipment calibration, physical and chemical test and analysis. Introduction to stream ecology, biological monitoring and macroinvertebrate taxonomy. In the field, macroinvertebrate, and fecal coliform sampling, habitat evaluation and personal safety will be covered.

All participants will be tested on their ability to perform designated monitoring tasks by the QA officer. Trainers will be present at all sampling sessions. With the assistance of the macroinvertebrate expert, volunteers will develop a reference collection that will be used in the lab to verify identifications of collected macroinvertebrates.

Documentation and Records

Each Lawsons Fork and Princess Creek Field Sheet must be completed on-site at the time of sampling.
Team members should make a copy of each Field Sheet and keep a copy with their records. The original is to be kept in the Lawsons Fork and Princess Creek Field Data Notebook.
Field Sheets must accompany all samples leaving the field and brought to the lab. After the macroinvertebrates are identified the macroinvertebrate identification sheet is kept in the Macroinvertebrate Identification Notebook. All notebooks are to be stored at Clemson University Department of Forest Resources Fecal coliform counts are kept in the Fecal Coliform Notebook and kept at the USC Spartanburg lab. All data is to be computerized within three months of sample date. A macroinvertebrate voucher collection is to be maintained by Clemson for 5 years.

MEASUREMENT/DATA ACQUISITION

Sampling Process Design

Sampling of Lawsons Fork and Princess Creek Watershed will follow an initial survey of the entire watershed (May 1999). During this stream survey volunteers and trainers will locate potential pollution sources which they will later monitor. Approximately ten sites will be selected. These sites will be monitored throughout the three years of the study. Each site will be given a specific identification number and the location will be recorded with GPS instrumentation and nearby street name or number.

Sampling will not be conducted within two days of a major rain event. Sampling will be conducted in teams of at least two persons. In stream macroinvertebrate sampling will be conducted for one half man hour at each site.

Prior to final site selection and sampling, permission to access the stream is obtained from all property owners if necessary.

Sampling Methods

Sampling Methods are as those described in EPA 841-B-97-003

Sample Handling and Custody

All macroinvertebrate and fecal coliform samples collected as part of the Lawsons Fork and Princess Creek Watershed Project are labeled in the field. The chain of custody for these samples is as follows:
In field, samples are responsibility of and stay with the field team captain.
Macroinvertebrate Samples: Samples are stored in ziplock style plastic bags in a cooler on ice. When sampling is complete, samples are returned to an off-stream site where volunteer gather to pick organisms from the detritus. The date and time of arrival at picking station is recorded by the team captain. Samples are processed, picked and identified immediately or are stored in a refrigerator at 5-10 C. Refrigerated samples must be identified within 24 hrs. or they must be preserved in 80% ethanol. A chain of custody form must accompany all transport and storage information.
Fecal Coliform Samples: Collection is as documented in EPA 841-B-97-003. Note that all water samples arestored on ice and processed within 6 hrs. A chain of custody form must accompany all transport and storage information.

Analytical Methods

In the Lawsons Fork and Princess Creek Project dissolved Oxygen is measured with a YSI model 51 dissolved oxygen meter. The meter is calibrated using YSI protocol. pH, and nitrate are measured using the Hach water quality test kit instructions. Macroinvertebrate, fecal coliform and habitat assessment methods and equipment are based on the protocols established by EPA in document EPA-841-B-97-003. Fecal coliform lab SOP is provided

Quality Control

Replicate samples for all chemical measurements are taken at three (randomly selected) sites. At least three of the macroinvertebrate samples will be reidentified by the laboratory leader during the lab session. Both a macroinvertebrate voucher and a reference collection will be maintained. If sampler problems are identified then the data is either thrown-out or qualified depending on the degree of the problem. Quality control for fecal coliform is achived by running lab replicates. All volunteers are retrained at least once per year in both lab and field procedures byClemson and USC Spartanburg personnel.

Instrument/Equipment Testing, Inspection, and Maintenance

Before usage thermometer mercury column is inspected for breaks. All DO meters are re-calibrated and tested for accuracy. All Hach Co. water quality test kits are checked for cleanliness and assurance that all chemicals and color comparators are in good condition. The field leader maintains a maintenance record logbook to track the maintenance on all equipment.

Instrument Calibration and Frequency

Dissolve Oxygen meter will be calibrated prior to each sampling day using the YSI manufacturers recommended techniques.

Inspection and Acceptance Requirements for Supplies

Lawsons Fork and Princess Creek Project participants will collect macroinvertebrates with kicknets having a mesh of 500 microns. Chemicals for the Hach water quality chemical kit will be reordered from Hach Co. when needed.

Data Acquisition

Macroinvertebrate assessment analysis, pollution tolerance values assigned to organisms and metric formulas are taken from the literature and documentation provided by EPA 841-B-97-003. USGS 7.5 minute maps are used to identify site locations (confirmed with GPS) land-use practices and landscape features during initial survey.

Data Management

Field data sheets are inspected and signed by the Field Team Leader before leaving the site. Field data sheets are given to the Field Manager at the end of sampling day for review. Within 72 hrs, Field Meader will contact any samplers whose sample sheets contain errors or omissions. Field Manager will review sample labels for macroinvertebrates and remove any that cannot be attributed to specific samplers, have not been properly preserved or exceed maximum holding time. Field Manager will sign-off on lab bench sheets after all QC checks have been completed. Fecal Coliform Lab Manager will review field sample labels for errors or omissions and remove any that cannot be corrected. Fecal Coliform Lab Manager will sign-off on all fecal coliform data sheets after QC checks have been completed.
Macroinvertebrate, water chemistry and habitat data sheets are stored at Clemson UniversityForest Resources lab. Fecal coliform data is strroed at USC Spartanburg. Bench sheets are stored in Bench Sheet Notebook at Laboratory. All data will be entered into Computerized database.

ASSESSMENT AND OVERSIGHT

Assessment and Response Actions

Review of field activities is the responsibility of the Field Manager in conjunction with the Project manager and Quality Assurance Officer. Each Field team will be accompanied by one of these individuals and evaluated once per year. Field team members may be retrained on site if necessary or if errors are consistent, retraining more frequently may become needed. All field and lab activities are reviewed annually by Project Leader, Field and Laboratory Advisors.

Reports

Reports are due 3 months after the quarterly sampling dates. An annual report is due in April of each year. Reports are sent to all cooperators.

DATA VALIDATION AND USABILITY

Data Review, Validation and Verification

All field and lab data is reviewed by the Project Manager, Field and Lab Managers and QA Officer to determine if the data meets QAPP objectives. State QA officer may be asked to review data.

Validation and Verification

In the field, any sample readings that appear out of the expected range are reported to the Field Leader. A second sample is collected by the Field Leader if he feels it is necessary. In the lab, 10-20% of macroinvertebrates are re-identified as a method to verify data. If an error of greater than 5% is found all samples are re-identified . Data entered into computerized data base must be printed and proofread against the original data sheets. Errors are to be corrected. Outliers and inconsistencies are to be flagged, reviewed and resolved. Problems with data quality will be discussed in the interim and final reports.

Reconciliation with Data Quality Objectives

As soon as possible after each sampling event, calculations and determinations for precision, completeness and accuracy will be made and corrective action implemented if needed. If necessary, data may be discarded and re-sampling may occur. Any limitations on data use will be detailed in both the interim and final reports.

APPENDIX A

Lab SOP for Fecal Coliform Monitoring

Membrane Filter Method

Definition - The indicator organism fecal coliform is tested by the filtering of a sample through a membrane filter that retains the bacteria. This method allows direct enumeration of the colonies. This information is used to the numbers of fecal coliforms present in water samples.

Apparatus:

Water bath - 44.5°C +/- 0.2°C
Binocular microscope - 10-15x
Fluorescent Lamp
Hand tally
Membrane filtration units
Vacuum source
Vacuum flask
Filter manifold
Forceps
Ethanol
Bunsen burner
Sterile pipets
Sterile petri dishes 50 x 9 F3000-50
Dilution bottles (milk), marked @ 99 ml
Membrane filters, Gelman GN-6 47 mm
Waterproof plastic bags
Ultraviolet sterilizer
M-FC Agar
Phosphate Buffer
Magnesium Chloride Solution
Culture tubes
Lauryl Sulfate Broth
EC Broth
Rosolic Acid
2N NaOH
Stirrer/hot plate
Inoculating loop
Sterile 250 ml sample bottles
Thermometer

Magnesium Chloride Solution

To make solution, add 81.8 grams of $MgCl_2 \cdot 6\ H_2O$ to 1000 ml of deionized H_2O.

Phosphate After Dilution Water

Stock Solution

Dissolved 34.0 grams of KH_2PO_4 in 500 ml of laboratory pure water. Adjust pH to 7.2 using 1N NaOH. Adjust the volume to 1,000 ml with laboratory pure water and autoclave 15 minutes at 121°C.

Store in refrigerator, until used. Dispose if solution becomes turbid or algae is seen.

Working Solution

Dispense 1.25 ml into 1,000 ml flask. Fill with laboratory pure water and mix. Add 5 ml of Magnesium Chloride Solution. Store in cool place without direct sunlight.

This solution is used for dilution water rinsing of membrance filters. It may be autoclaved in dispensers for 15 minutes at 121°C. This solution cannot be used the same day that it is made. Store in a dark location.

For use with dilution technique, dispense 102 ml of working solution water into milk dilution bottles and autoclave 15 minutes at 121°C (with lids loosened). Final volume will be 99 +/- 2 ml. Tighten caps after sterilization and store in a dark, cool place. Dispose of solution if turbid or algae is seen.

Media:

M FC Agar (BBL)

For enumeration of Fecal Coliform by Membrane Filter Procedure.

Prepare by adding 5.2 grams of agar per 100 m. Dissolve 0.1 grams of rosolic acid in 1 ml of 0.2N NaOH. Add to agar solution/100 ml. Heat to boiling. Cool solution to 45°C and pour agar into petri dishes at 2-3 mm minimum depth. Allow to solidify. May be stored at 4°C for 2 weeks. Final pH should be 7.2 +/- 0.2.

*0.2 N Sodium Hydroxide
1.6 ml of 50% NaOH into 100 ml of laboratory pure water. Autoclave 15 minutes at 121°C. Store indefinitely in cooler.

Lauryl Sulfate Broth (BBL)

Primary medium for Presumptive Test for coliform group.

Add 35.6 grams of the LSB medium to 1 liter of laboratory pure water and mix to dissolve.

Dispense 10 ml into fermentation tubes (150 x 20 mm test tubes containing 75 x 10 mm durham tubes). Autoclave 15 minutes at 121°C with loosened caps. Cool quickly and tighten caps. Final pH is 6.8 +/- 0.2. Store in cooler up to 3 months.

<u>EC Medium (BBL)</u>

Add 37 grams of EC medium to 1 liter of laboratory pure water and mix.

Dispense into fermentation tubes (150 x 20 mm test tubes containing 75 x 10 mm durham tubes).

Autoclave 15 minutes at 121°C with loosened caps. Cool quickly and tighten caps. Final pH is 6.9 +/- 0.2. Store in cooler up to 3 months.

Sterilize sample bottles in the autoclave at 121°C for 15 minutes. Label with proper lot # and store for use.

Procedure

Disinfect work area by spraying with Ethanol and allowing to dry. Unwrap the sterilized filtration units and place in the ultraviolet light box (UV). Turn UV lamp on, close box and sterilize unit for 5 minutes. Forceps may be sterilized by immersing the tips in ethanol and flaming. Identify each dish with sample ID and dilution volume. Negative control - using sterile forceps. Remove filter receptacle from UV box and place membrane on porous presterilized filter base, grid side up. Place funnel in position. Filter 40 ml of sterile Phospate buffer solution. This is the quality control sample necessary to provide the integrity of the sterility of the units and buffer. Apply the vacuum. After filtration, remove the funnel. Utilizing sterile forceps, remove the membrane and place gently, in a rolling motion, onto the MFC agar petri dish. Close petri dish, invert and incubate.

Return filtration unit to UV box and sterilize for 3 minutes.

Sample filtration - Remove a filter receptacle from the UV Box. Place a membrane on the filter base and attach funnel. Shake the sample 25 times. A sample volume is selected to yield an estimated colony count between 20 and 60 colonies.

Samples larger than 10 ml; measure the sample in the sterile, graduated funnel. Rinse the graduated funnel twice with dilution water.

Samples 10 ml; pour 10 ml of dilution water into funnel; then directly pipes amount desired.

(c) Samples less than 1.0 ml; transfer a 1 ml volume to a prepared 99 ml buffered dilution water bottle. Shake well 25 times. Withdraw 1.0 ml or 0.1 ml for testing. Place selected volume aseptically into filtration unit and turn on vacuum. After filtration of sample, rinse the membrane and sides of funnel gently with 3 aloquotes of 25 ml portions of sterile phosphate buffer solution and allow to filter. Disengage vacuum and remove funnel. Utilizing sterile forceps, remove membrane filter and place on MFC agar with a rolling motion which excludes air bubbles underneath. Close petri dish, invert and incubate. Positive Control - positive control sample is to be incubated at the end. Place a UV sterilized filter receptacle onto manifold, aseptically place membrane onto porous base and attach the funnel. Place approximately 20 ml of phosphate buffer onto membrane. With a dropper, place 2 or 3 drops of a known sample that contains the E. coli bacteria. Apply vacuum, rinse with 2 more 25 ml volumes of phosphate buffer. After filration, remove membrane and place properly on an agar plate. Invert and incubate. Negative Control 2 - Prepare another Negative Control at the end of the process to ascertain if aseptic conditions were followed and cross contamination did not occur. (See negative control above.) If found, invalidate test. Return filtration units to UV box and end with 5 minutes of sterilization. Units may now be washed, wrapped properly with Kraft paper and sterilized. See autoclave instructions under Equipment section.

Incubation: Place cultures in a waterproof bag and submerge in a water bath incubator preheated to 44.5 +/- 0.2°C for 24 +/- 2 hours. All prepared cultures must be incubated within 30 minutes of filtration.

Counting:

Count the colonies using the grid lines. E. coli colonies will be smooth, round, and blue, easily seen with the binocular microscope. Illumination is provided by the fluorescent lamp that is perpendicular to the membrane.

Select the membrane filter within acceptable range of 20 to 60 colonies. Report as:

No. of colonies counted

x count per 100 ml = Volume of Sample Filtered x 100

* If more than 1 acceptable limit exists, average the numbers and report.

* If all the filters are below the limit, select the most nearly acceptable and report as estimated count.

For example, if volumes of 25, 10, and 2 ml produced 0, 0, and 0, then no actual calculation is possible. Report the number of colonies as if one colony were present on the largest volume. In this instance, it would be

$$\frac{1 \text{ ml} \times 100}{25} = 4$$

Report as: 4 colonies per 100 ml.

* If all membranes are above the upper limit, calculate using the smallest volume.

For example, if the volumes of 1, 0.3, and 0.01 ml produce TNTC, 150 and 110 respectively, calculate as follows: Utilize plate with most acceptable: 110.

$$\frac{10 \times 110}{0.01} = 110{,}000$$

Report as an estimated count of 1,100,000 colonies per 100 ml.

If all the membranes produced TNTC, it may upper limit be reported using 60 as the base.

$$\frac{60 \times 100}{0.01} = >6{,}000{,}000$$

Holding Time:

Samples may be held for 6 hours at 4°C.

Reference:
Standard Methods
17th Edition

Microbiological Methods for Monitoring the Environment EPA 600/8-78-017.

VERIFICATION OF FECAL COLIFORM COLONIES

Definition - A confirmed technique for verifying results of membrane filter testing: utilizing Lauryl Sulfate Broth (LSB), the organism is enriched; then using EC Media the culture is stressed.

Certification requires 2 to 5 percent verification.

Apparatus:

Water bath - 44.5°C +/- 0.02°C

Dry Incubator - 35°C +/- 0.5°C
Lauryl sulfate broth
E.C. Media
Inoculating Loop 3 mm
Bunsen burner

Methanol

Procedure: This process is twofold.

LSB:

Sterilize inoculating loop by immersing in methanol and flaming using bunsen burner. Allow to cool. Using the dissecting microscope, select an isolated colony that was recovered on MFC media and transfer to a fermentation tube of LSB by gently submersing the loop 1 inch below surface. Replace screw cap loosely and incubate @ 35°C +/- 0.5°C for 24a hours in dry incubator. Re-flame loop to kill bacteria.

Remove all gas positive tubes and re-incubate all negative tubes for an additional 24 hours. All tests which fail to produce gas positive reactions within 48 hours are non-coliforms.

EC:

Step two requires the gas positive tubes to be transferred to EC media. Immerse a flamed sterilized loop into the positive LTB tube and transfer to an EC fermentation tube. Replace screw cap loosely. Re-flame loop to kill bacteria. Incubate the EC tubes at 44.5°C +/- 0.2°C for 24 hours in the water bath.

Remove tubes from incubator. All gas positive tubes are E. coli bacteria. Eliminate from the final tally any colony failing the confirming verification procedure.

Autoclave glass tubes before washing and plastic petri dishes before disposal.

Reference:

Standard Methods
19th Edition 1995

Procedure

Disinfect work area by spraying with Ethanol and allowing to dry. Unwrap the sterilized filtration units and place in the ultraviolet light box (UV). Turn UV lamp on, close box and sterilize unit for 5 minutes. Forceps may be sterilized by immersing the tips in ethanol and flaming. Identify each dish with sample ID and dilution volume. Negative control - using sterile forceps. Remove filter receptacle from UV box and place membrane on porous presterilized filter base, grid side up. Place funnel in position. Filter 40 ml of sterile Phosphate buffer solution. This is the quality control sample necessary to provide the integrity of the sterility of the units and buffer. Apply the vacuum. After filtration, remove the funnel. Utilizing sterile forceps, remove the membrane and place gently, in a rolling motion, onto the MFC agar petri dish. Close petri dish, invert and incubate.

Return filtration units to UV box and end with 5 minutes of sterilization. Units may now be washed, wrapped properly with Kraft paper and sterilized.

Incubation: Place cultures in a waterproof bag and submerge in a water bath incubator preheated to 44.5 +/- 0.2°C for 24 +/- 2 hours. All prepared cultures must be incubated within 30 minutes of filtration.

Counting:

Count the colonies using the grid lines. E. coli colonies will be smooth round, and blue, easily seen with the binocular microscope. Illumination is provided by the fluorescent lamp that is perpendicular to the membrane.

Reference: Standard Methods, 19th Edition

Microbiological Methods for Monitoring the Environment EPA 600/8-78-017

APPENDIX C EXAMPLE 2

QUALITY ASSURANCE PLAN

Rawls Creek NPS Assessment & Community Education Project

Requesting organization:

South Carolina Department of Natural Resources
Bill Marshall, Coordinator of Planning and Research
2221 Devine Street, Suite 222
Columbia, SC 29205
803.734.9096
marshall@water.dnr.state.sc.us

Date of request: 06 November 1998
Project start date: 01 June 1999

William D Marshall 6/07/99
Bill Marshall Date
Project Officer
South Carolina Department of Natural Resources

Daniel L Tufford 6/2/99
Dan Tufford Date
Quality Assurance Officer
University of South Carolina

Distribution list

SC Department of Health and Environmental Control
Project Coordinator - Bill Marshall
Project QA Officer - Dan Tufford

2. Project description - See Appendix A for the overall description. The objective of the field sampling phase of this project is to identify nonpoint sources (NPS) or hot-spots of fecal loading into Rawls Creek. NPS loads are normally associated with rainfall runoff, so this phase will first identify locations within the watershed that may be expected to contribute a significant amount of runoff to the Creek. We will establish a network of approximately 10 stations (see item 6.1 for details). Then baseflow and stormflow sampling will take place. We will sample the sites twice during baseflow conditions and also during six storm flow conditions. The baseflow sampling will establish base concentrations of fecal pollution at each sample site. Statistical and spatial analysis of stormflow concentrations will reveal subareas within the watershed that are significant sources of NPS fecal loading, if they exist.
3. Schedule of tasks and products - see Appendix B
4. Project organization and responsibility - see Appendix A for the overall project. Dan Tufford (USC) is primarily responsible for the stream sample collection and analysis. Bill Marshall (SCDNR) and Dan Tufford are responsible for sample site selection. Dan, Bill, and other SCDNR staff will make up the field sampling teams.
5. Data quality requirements and assessments - This project will be collecting stream water samples for analysis for fecal coliform concentration. There are potential regulatory implications from this, so it is necessary the analysis be conducted according to USEPA approved methods by a State certified laboratory. The samples will be analyzed using the membrane filter technique, Standard Methods 9222D. Results are reported as # colonies per 100-ml. The analysis will be performed by:

   Columbia Analytical Laboratories, Inc.
   3005 Broad River Road
   Columbia, SC 29210
   803.561.0331
   Contact: Greg Mullinax

6. Sampling procedures
   6.1. Specific sampling site selection - In suburbanized watersheds, NPS fecal loading may occur from many sources. Among them are septic systems, isolated pockets of forest or fields (such as greenways, parks, or golf courses) where wildlife may be concentrated, structures such as storm drains or drainage ditches, outflow from rainfall detention/retention ponds, and surface runoff from large impervious surfaces. We will determine the storm drainage structure and land use/land cover of the watershed with the use of county infrastructure data, existing GIS data layers, and published results of prior work. We will evaluate these data to select approximately 10 sampling sites that will help identify or isolate areas within the watershed that are significantly contributing to

fecal loading. Because of the need to reach sample sites relatively quickly during storm runoff events, accessibility from existing roads and parking lots will be another criterion for site selection.

6.2. Storage containers - The sample containers, 125-ml sterile glass bottles, are provided by Columbia Analytical. Containers will be filled by dipping them below the water surface layer.

6.3. Special precautions - As soon as a sample is taken it will be put in a cooler on ice (4 C) for transport to Columbia Analytical. Maximum holding time prior to analysis is 6-hours. We estimate a round of sampling will take no more than 2-hours. We will notify Columbia Analytical of our intention to sample prior to leaving for the field so that they will be alerted to the need to have staff available for sample analysis.

7. Sample custody procedures - The project team members that collect the samples will be responsible for taking them to Columbia Analytical. A chain-of-custody form is provided by Columbia Analytical. They will not accept for processing any samples that are not accompanied by properly executed forms. Forms will be returned to us by Columbia Analytical along with the analytical results.

8. Instrument selection - This is not applicable for the field work. See the attached Standard Operating Procedures for Columbia Analytical for other details (Appendix C).

9. Safety - There are no special safety procedures associated with the stream sampling. Normal traffic safety procedures will be followed for parking vehicles and crossing roadways (if needed).

10. Documentation - (a) A sampling log form will be developed for use by the sample collection teams. These will record the sampling day, time of day at each station, weather conditions, and any special notes of potential importance such as unusual conditions. (b) No special data reduction or reporting is needed. All field sampling notes, analytical results, and chain-of-custody forms will be maintained by Dan Tufford in a project file at the University of South Carolina, Department of Environmental Health Sciences.

11. Data validation - This function is performed by Columbia Analytical Laboratories, Inc..

12. Performance and system audits - (a) At the conclusion of each sample trip, all participating team members will be polled for information on problems (actual or potential) encountered. Among the issues of potential concern is that we may determine our sample site selection is not optimal for achieving our objectives. (b) Each time the analytical results and chain-of-custody forms are returned from Columbia Analytical they will be reviewed for problems, such as exceedence of the 6-hour sample holding time.

13. Corrective action - In the event a problem is identified in (12) above, steps to correct the problem will be identified and implemented prior to the next sampling trip. If the problem is with Columbia Analytical and an acceptable solution cannot be implemented, a different commercial laboratory will be selected for the remaining sample analyses.

14. Reports - When the field sampling phase of the project is complete the results will be analyzed statistically (e.g. analysis of variance) and with respect to land uses. The analysis will include conclusions, if any, about the location and source-type of fecal loading in the watershed.

Rawls Creek NPS Assessment & Community Education Project:

Milestones and Associated Tasks: Assumed Start Date: June 1, 1999

Draft: April 28, 1999

Project Start-up Tasks: May 1 to May 30

- Contract with Dan Tufford at USC
- Contract (or subcontract) with Columbia Analytical Laboratories
- Contract with Congaree Land Trust
- Recruit prospective youth groups for Fall events through contact with leaders and teachers

Milestone 1: Submit a QA/QC plan for WQ monitoring and analyses to SCDHEC (June 1).
Tasks: May 1 to May 30

- Coordinate and write QA/QC plan for WQ monitoring and analysis

Milestone 2: Complete assessment of land uses (June 30). Product: Report describing LU/LC in Rawls Creek watershed and defining locations of probable NPS fecal coliform contamination to Rawls Creek (later to be combined with WQ monitoring findings to produce a single report).
Tasks: June 1 to June 30

- Access and analyze available maps and 1994 NAPP photos.
- Conduct field surveys and stream walks; document findings.
- Inventory area of LU/LC categories and potential NPS fecal coliform contamination.
- Write preliminary report of findings.

Milestone 3: Complete production of public information materials (August 31). Products: (1) Two posters of photo mosaics: Rawls Creek watershed and lower Saluda River watershed; (2) Five thousand copies of a booklet describing BMPs for residential homeowners and businesses to protect stream habitats and water quality.
Tasks: June 1 to August 31

- Research potential concept, design, and content for BMP booklet.
- Outline and draft BMP booklet text and graphics for review and comment.
- Finalize text and design of BMP booklet.
- Procure services of commercial printer to produce BMP booklet.
- Access all photos needed for posters.
- Procure services of commercial vendor to produce posters.

Milestone 4: Complete water quality monitoring (August 31). Product: Preliminary report describing NPS water quality conditions, the LU/LC assessment findings, and conclusions regarding the probable locations and sources of fecal coliform pollution problems and alternative solutions for mitigating the problems.
Tasks: June 1 to August 31

- Select and establish 10 WQ monitoring stations.
- Define field procedures and train staff/volunteers: sample collection, monitoring with meters, recording data, QA/QC.
- Field test procedures. Monitor and sample non-storm WQ conditions.
- Conduct WQ monitoring and sampling at the 10 stations for six storm events.
- Analyze WQ monitoring data.
- Compare WQ findings with land use assessment.
- Write preliminary report of findings.

Milestone 5: Complete inventory of landowners (August 31). Product: List of names and addresses for property owners associated with nonpoint source areas of fecal coliform bacteria and selected property owners adjacent to streams in Rawls Creek watershed.

Tasks: August 1 to August 31

- Access parcel maps and inventory land ownership in selected areas based on preliminary findings of LU/LC assessment and WQ monitoring

Milestone 6: Complete youth education and outreach event (September 30). Products: (1) Five to ten presentations about watersheds and nonpoint source pollution to area youth groups: scout troops and high school classes; (2) Community-outreach field day for the youth groups: distributing information throughout the community rewarded with a cookout at Saluda Shoals Park and canoeing on the lower Saluda River.

Tasks: August 1 to September 30

- Schedule and conduct meetings/presentations with groups at beginning of school year.
- Schedule and organize outreach event: information packets and distribution logistics.
- Organize cookout and canoeing logistics.

Milestone 7: Complete Landowner education and outreach event (October 30). Product: Invitational dinner held at Saluda Shoals Park for selected stream-side landowners and community leaders to increase awareness of best management practices and conservation to protect stream habitats and water quality.

Tasks: September 15 to October 30

- Schedule and organize outreach event and mail invitations.
- Organize dinner and program logistics, prepare information and presentations.

Milestone 8: Submit final project report to SCDHEC (Month 12).

Tasks: November 1, 1999 to May 30, 2000

- Produce final maps and graphics.
- Write final report.
- Compile additional information as required by SCDHEC.

CHAIN-OF-CUSTODY/SAMPLE COLLECTION/ANALYSIS REQUEST

Client Name: ______	Project Name: ______
Report To: ______	Invoice To: ______
Address: ______	Address: ______
City / St. / Zip: ______	City / St. / Zip: ______
Phone / Fax: ______	Phone / Fax: ______
Contact: ______	Contact: ______

Columbia Analytical Laboratories, Inc.

3005 Broad River Road
Columbia, SC 29210
Bus: 803-561-0331 Fax: 803-561-0536

JOB #

Fax Report (circle) Yes No

Your C.A.L. Project Manager:

C.A.L. SCDHEC #40001

Sampler Signature: ______ Sample Location	GRAB OR COMPOSITE SAMPLING INFO: Time / Date ON 19__	Time / Date OFF	composite	grab	# Bottles: sampled	received	subcontracted	Program Area: NPDES	SDWA	RCRA	Industrial Pretreatment	other	Matrix: soil	liquid	solid waste	Tests Requested
	/	/														
	/	/														
	/	/														
	/	/														
	/	/														
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Samples received preserved with HNO3: ___ Metals

Samples received preserved with H2SO4: ___ O/G ___ NH4 ___ COD ___ NO3-NO2 ___ TKN ___ TOC ___ Phel ___ TPO4

Samples received preserved with HCL: ___ VOC

Samples received preserved at 4 deg. C: ___ GI ___ FC/TC ___ BNA

Samples received preserved with NaOH: ___ CN

Samples received preserved with NaOH/ZnOAc: ___ Sulfide

Were Samples Preserved in Ice?(circle) Yes No

Relinquished by:	Date	Time	Received by:	Date	Time
Relinquished by:	Date	Time	Received by:	Date	Time
Relinquished by:	Date	Time	Received by C.A.L.	Date	Time

Comments:

Sample ID No. ______

BACTERIOLOGICAL CHAIN-OF-CUSTODY RECORD

Columbia Analytical Laboratories, Inc.

3005 Broad River Road
Columbia, SC 29210
Bus: 803-561-0331 Fax: 803-561-0536

LAB USE ONLY:

Sample ID # ____________________

Job # ____________________

SPECIFY WHO IS RESPONSIBLE FOR PAYMENT:

Report To: ____________________ **Invoice To:** ____________________
Address: ____________________ **Address:** ____________________
City/St./Zip ____________________ **City/St./Zip** ____________________
Phone/Fax ____________________ **Phone/Fax** ____________________
Contact ____________________ **Contact** ____________________

Will Pick-up Report ________ Please Fax Report (circle) Yes No **Fax Charge is $5.00**
Please Mail Report ________

*All Samples received after 12:00 pm on Thursdavs OR Davs Preceeding C.A.L. honored holidavs will be double priced.

Sample Location	Sampler Name	Date Collected	Time Collected	TC	Present or Absent	FC	Present or Absent

Comments

____ Exceeded Holding Time ________ repeat
____ TC ____ On Ice
____ FC ____ Other ________

Relenquished by:	Date	Time	Received by:	Date	Time
Relenquished by:	Date	Time	Received by C.A.L.:	Date	Time

APPENDIX D

DATA QUALITY INDICATORS

INTRODUCTION

Data Quality Indicators (DQIs) are qualitative and quantitative descriptors used in interpreting the degree of acceptability or utility of data. The principal DQIs are precision, bias, representativeness, comparability, and completeness. Secondary DQIs include sensitivity, recovery, memory effects, limit of quantitation, repeatability, and reproducibility. Establishing acceptance criteria for the DQIs sets quantitative goals for the quality of data generated in the analytical measurement process. DQIs may be expressed for entire measurement systems, but it is customary to allow DQIs to be applied only to laboratory measurement processes. The issues of design and sampling errors, the most influential components of variability, are discussed separately in EPA QA/G-5S, *Guidance on Sampling Designs to Support QAPPs.*

Of the five principal DQIs, precision and bias are the quantitative measures, representativeness and comparability are qualitative, and completeness is a combination of both quantitative and qualitative measures.

The five principal DQIs are also referred to by the acronym PARCC, with the "A" in PARCC referring to accuracy instead of bias. This inconsistency results because some analysts believe accuracy and bias are synonymous, and PARCC is a more convenient acronym than PBRCC. Accuracy comprises both random error (precision) and systematic error (bias), and these indicators are discussed separately in this appendix. DQIs are discussed at length in EPA QA/G-5I, *Guidance on Data Quality Indicators*.

AD1. PRINCIPAL DQIs: PARCC

AD1.1 PARCC: Precision

Precision is a measure of agreement among replicate measurements of the same property, under prescribed similar conditions. This agreement is calculated as either the range (R) or as the standard deviation (s). It may also be expressed as a percentage of the mean of the measurements, such as relative range (RR) (for duplicates) or relative standard deviation (RSD).

For analytical procedures, precision may be specified as either **intra**laboratory (within a laboratory) or **inter**laboratory (between laboratories) precision. Intralaboratory precision estimates represent the agreement expected when a single laboratory uses the same method to make repeated measurements of the same sample. Interlaboratory precision refers to the agreement expected when two or more laboratories analyze the same or identical samples with the same method. Intralaboratory precision is more commonly reported; however, where available, both intralaboratory and interlaboratory precision are listed in the data compilation.

When possible, a sample subdivided in the field and preserved separately is used to assess the variability of sample handling, preservation, and storage along with the variability of the analysis process.

When collocated samples are collected, processed, and analyzed by the same organization, intralaboratory precision information on sample acquisition, handling, shipping, storage, preparation. and analysis is obtained. Both samples can be carried through the steps in the measurement process together to provide an estimate of short-term precision. Likewise, the two samples, if separated and processed at different times or by different people and/or analyzed using different instruments, provide an estimate of long-term precision.

AD1.2 PARCC: Bias

Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction. Bias assessments for environmental measurements are made using personnel, equipment, and spiking materials or reference materials as independent as possible from those used in the calibration of the measurement system. When possible, bias assessments should be based on analysis of spiked samples rather than reference materials so that the effect of the matrix on recovery is incorporated into the assessment. A documented spiking protocol and consistency in following that protocol are important to obtaining meaningful data quality estimates. Spikes should be added at different concentration levels to cover the range of expected sample concentrations. For some measurement systems (e.g., continuous analyzers used to measure pollutants in ambient air), spiking samples may not be practical, so assessments should be made using appropriate blind reference materials.

For certain multianalyte methods, bias assessments may be complicated by interferences among multiple analytes, which prevents all of the analytes from being spiked into a single sample. For such methods, lower spiking frequencies can be employed for analytes that are seldom or never found. The use of spiked surrogate compounds for multianalyte gas chromatography/ mass spectrometry (GC/MS) procedures, while not ideal, may be the best available procedure for assessment of bias.

AD1.3 PARCC: Accuracy

Accuracy is a measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that result from sampling and analytical operations.

Accuracy is determined by analyzing a reference material of known pollutant concentration or by reanalyzing a sample to which a material of known concentration or amount of pollutant has been added. Accuracy is usually expressed either as a percent recovery (P) or as a percent bias (P - 100). Determination of accuracy always includes the effects of variability (precision); therefore, accuracy is used as a combination of bias and precision. The combination is known statistically as mean square error.

Mean square error (MSE) is the quantitative term for overall quality of individual measurements or estimators. To be accurate, data must be both precise and unbiased. Using the analogy of archery, to be accurate, one must have one's arrows land close together and, on average, at the spot where they are aimed. That is, the arrows must all land near the bull's-eye (see Figure AD.1).

Mean square error is the sum of the variance plus the square of the bias. (The bias is squared to eliminate concern over whether the bias is positive or negative.) Frequently, it is impossible to quantify all of the components of the mean square error--especially the biases--but it is important to attempt to quantify the magnitude of such potential biases, often by comparison with auxiliary data.

AD1.4 PARCC: Representativeness

Representativeness is a measure of the degree to which data accurately and precisely represent a characteristic of a population parameter at a sampling point or for a process condition or environmental

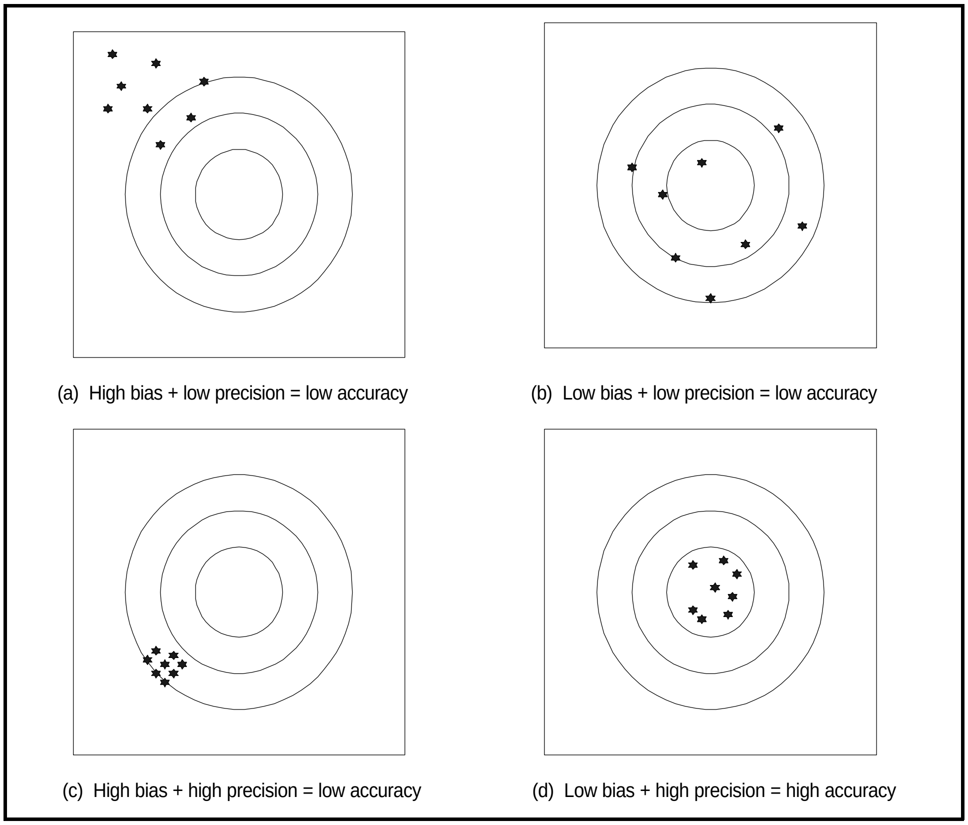

Figure AD1. Measurement Bias and Random Measurement Uncertainties: Shots at a Target

condition. Representativeness is a qualitative term that should be evaluated to determine whether in situ and other measurements are made and physical samples collected in such a manner that the resulting data appropriately reflect the media and phenomenon measured or studied.

AD1.5 PARCC: Comparability

Comparability is the qualitative term that expresses the confidence that two data sets can contribute to a common analysis and interpolation. Comparability must be carefully evaluated to establish whether two data sets can be considered equivalent in regard to the measurement of a specific variable or groups of variables. In a laboratory analysis, the term comparability focuses on method type comparison, holding times, stability issues, and aspects of overall analytical quantitation.

There are a number of issues that can make two data sets comparable, and the presence of each of the following items enhances their comparability:

- two data sets should contain the same set of variables of interest;
- units in which these variables were measured should be convertible to a common metric;
- similar analytic procedures and quality assurance should be used to collect data for both data sets;
- time of measurements of certain characteristics (variables) should be similar for both data sets;

- measuring devices used for both data sets should have approximately similar detection levels;
- rules for excluding certain types of observations from both samples should be similar;
- samples within data sets should be selected in a similar manner;
- sampling frames from which the samples were selected should be similar; and
- number of observations in both data sets should be of the same order or magnitude.

These characteristics vary in importance depending on the final use of the data. The closer two data sets are with regard to these characteristics, the more appropriate it will be to compare them. Large differences between characteristics may be of only minor importance, depending on the decision that is to be made from the data.

Comparability is very important when conducting meta-analysis, which combines the results of numerous studies to identify commonalities that are then hypothesized to hold over a range of experimental conditions. Meta-analysis can be very misleading if the studies being evaluated are not truly comparable. Without proper consideration of comparability, the findings of the meta-analysis may be due to an artifact of methodological differences among the studies rather than due to differences in experimentally controlled conditions. The use of expert opinion to classify the importance of differences in characteristics among data sets is invaluable.

AD1.6 PARCC: Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system, expressed as a percentage of the number of valid measurements that should have been collected (i.e., measurements that were planned to be collected).

Completeness is not intended to be a measure of representativeness; that is, it does not describe how closely the measured results reflect the actual concentration or distribution of the pollutant in the media sampled. A project could produce 100% data completeness (i.e., all samples planned were actually collected and found to be valid), but the results may not be representative of the pollutant concentration actually present.

Alternatively, there could be only 70% data completeness (30% lost or found invalid), but, due to the nature of the sample design, the results could still be representative of the target population and yield valid estimates. Lack of completeness is a vital concern with stratified sampling. Substantial incomplete sampling of one or more strata can seriously compromise the validity of conclusions from the study. In other situations (for example, simple random sampling of a relatively homogeneous medium), lack of completeness results only in a loss of statistical power. The degree to which lack of completeness affects the outcome of the study is a function of many variables ranging from deficiencies in the number of field samples acquired to failure to analyze as many replications as deemed necessary by the QAPP and DQOs. The intensity of effect due to incompleteness of data is sometimes best expressed as a qualitative measure and not just as a quantitative percentage.

Completeness can have an effect on the DQO parameters. Lack of completeness may require reconsideration of the limits for the false negative and positive error rates because insufficient completeness will decrease the power of the statistical test.

The following four situations demonstrate the importance of considering the planned use of the data when determining the completeness of a study. The purpose of the study is to determine whether the average concentration of dioxin in surface soil is no more than 1.0 ppb. The DQOs specified that the sample average should estimate the true average concentration to within ±0.30 ppb with 95 % confidence. The resulting sampling design called for 30 samples to be drawn according to a simple random sampling scheme. The results were as follows:

	Study result	Completeness	Outcome
1.	1.5 ppb ± 0.28 ppb	97%	satisfies DQOs and study purpose
2.	500 ppb ± 0.28 ppb	87%	satisfies DQOs and study purpose
3.	1.5 ppb ± 0.60 ppb	93%	doesn't satisfy either
4.	500 ppb ± 0.60 ppb	67%	fails DQOs but meets study purpose

For all but the third situation, the data that were collected completely achieved their purpose, meeting data quality requirements originally set out, or providing a conclusive answer to the study question. The degree of incompleteness did not affect some situations (situations 2 and 4) but may have been a prime cause for situation 3 to fail the DQO requirements. Expert opinion would then be required to ascertain if further samples for situation 3 would be necessary in order to meet the established DQOs.

Several factors may result in lack of completeness: (1) the DQOs may have been based on poor assumptions, (2) the survey design may have been poorly implemented, or (3) the design may have proven impossible to carry out given resource limitations. Lack of completeness should always be investigated, and the lessons learned from conducting the study should be incorporated into the planning of future studies.

AD2. OTHER DATA QUALITY INDICATORS

AD2.1 Sensitivity

Sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest. Sensitivity is determined from the value of the standard deviation at the concentration level of interest. It represents the minimum difference in concentration that can be distinguished between two samples with a high degree of confidence.

AD2.2 Recovery

Recovery is an indicator of bias in a measurement. This is best evaluated by the measurement of reference materials or other samples of known composition. In the absence of reference materials, spikes or surrogates may be added to the sample matrix. The recovery is often stated as the percentage measured with respect to what was added. Complete recovery (100%) is the ultimate goal. At a minimum, recoveries should be constant and should not differ significantly from an acceptable value. This means that control charts or some other means should be used for verification. Significantly low recoveries should be pointed out, and any corrections made for recovery should be stated explicitly.

AD2.3 Memory Effects

A memory effect occurs when a relatively high-concentration sample influences the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument. This represents a fault in an analytical measurement system that reduces accuracy.

AD2.4 Limit of Quantitation

The limit of quantitation is the minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

AD2.5 Repeatability

Repeatability is the degree of agreement between independent test results produced by the same analyst using the same test method and equipment on random aliquots of the same sample within a short time period.

AD2.6 Reproducibility

Reproducibility is the precision that measures the variability among the results of measurements of the same sample at different laboratories. It is usually expressed as a variance and low values of variance indicate a high degree of reproducibility.

AD2.7 DQIs and the QAPP

At a minimum, the following DQIs should be addressed in the QAPP: accuracy and/or bias, precision, completeness, comparability, and representativeness. Accuracy (or bias), precision, completeness, and comparability should be addressed in Section A7.3, Specifying Measurement Performance Criteria. Refer to that section of the G-5 text for a discussion of the information to present and a suggested format. Representativeness should be discussed in Sections B4.2 (Subsampling) and B1 (Sampling Design).

Table AD1. Principal Types of Error

Types of Error	Sources of Error
Random Error (precision; "P" in PARCC)	Natural variability in the population from which the sample is taken. Measurement system variability, introduced at each step of sample handling and measurement processes.
Systematic Error (accuracy/bias; "A" in PARCC)	Interferences that are present in sample matrix. Loss (or addition) of contaminants during sample collection and handling. Loss (or addition) of contaminants during sample preparation and analysis. Calibration error or drift in the response function estimated by the calibration curve.

Lack of representativeness ("R" in PARCC)	Sample is not representative of the population, which often occurs in judgmental sampling because not all the units of the population have equal or known selection probabilities. Sample collection method does not extract the material from its natural setting in a way that accurately captures the desired qualities to be measured. Subsample (taken from a sample for chemical analysis) is not representative of the sample, which occurs because the sample is not homogeneous and the subsample is taken from the most readily available portion of the sample. Consequently, other parts of the sample had less chance of being selected for analysis.
Lack of comparability ("C" in PARCC)	Failure to use similar data collection methods, analytical procedures, and QA protocols. Failure to measure the same parameters over different data sets.
Lack of completeness ("C" in PARCC)	Lack of completeness sometimes caused by loss of a sample, loss of data, or inability to collect the planned number of samples. Incompleteness also occurs when data are discarded because they are of unknown or unacceptable quality.

AD2.8 References

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APPENDIX E

PROVIDERS OF PROFICIENCY TESTING

(See website: **http://ts.nist.gov/ts/htdocs/210/214/scopes/calchem.htm**)

Absolute Standards, Inc.
Mr. Stephen Arpie
P.O. Box 5585
Hamden, CT 06518-0585
Phone: (203) 281-2917
Fax: (203) 281-2922
E-mail: absolutest@aol.com

AccuStandard, Inc.
Mr. William McCain
125 Market Street
New Haven, CT 06513-3031
Phone: (203) 786-5290 ext. 102
Fax: (203) 786-5287
E-mail: bm@accustandard.com

Analytical Products Group, Inc.
Mr. Thomas V. Coyner
2730 Washington Boulevard
Belpre, OH 45714
Phone: (740) 423-4200
Fax: (740) 423-5588
E-mail: APG@citynet.net

Chrisope Technologies, A Division of Remel
Ms. Jody D. Moss
3941 Ryan Street
Lake Charles, LA 70605
Phone: (318) 479-1000 ext 236
Fax: (318) 479-1006
E-mail: jdmoss@remelinc.com

Environmental Resource Associates (ERA)
Charles Wibby
5540 Marshall Street
Arvada, CO 80002
Phone: (303) 431-8454
Fax: (303) 421-0159
E-mail: eracxw@aol.com

Microcheck, Inc.
Dr. Michael G. Sinclair
9 School Circle
Northfield Falls, VT 05664
Phone: (802) 485-6600 ext. 22
Fax: (802) 485-6100
E-mail: micro@microcheck.com

NSI Solutions, Inc. - NC Office
Melissa Levadnuk
2 Triangle Drive
RTP, NC 27709
Phone: (800) 234-7837 or (919) 549-8980
Fax: (919) 544-0334

NYS DOH Environmental Laboratory Approval Program
Mr. Kenneth W. Jackson
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509
Phone: (518) 485-5570
Fax: (518) 485-5568
E-mail: jackson@wadsworth.org

Protocol Analytical Supplies, Inc.
Mr. William H. Hahn, Jr.
472 Lincoln Blvd.
Middlesex, NJ 08846
Phone: (732) 627-0500
Fax: (732) 627-0979
E-mail: bhahn@prostds.com

Spex Certiprep, Inc.
Dr. Vanaja Sivakumar
203 Norcross Ave.
Metuchen, NJ 08840
Phone: (732) 549-7144 ext. 418
Fax: (732) 494-1747
E-mail: vsivakumar@spexcsp.com

Ultra Scientific, Inc.
Mr. Edward F. Martz
250 Smith Street
North Kingston, RI 02852-7723
Phone: (401) 294-9400
Fax: (401) 295-2330
E-mail: emartz@ultrasci.com

APPENDIX F

Table AA2. Quality System Documents

Overview	
QA/G-0	EPA Quality System Description
Program level	
QA/R-1	EPA Quality Systems Requirements for Environmental Programs
QA/G-1	Guidance for Developing Quality Systems for Environmental Data Operations
QA/R-2	EPA Requirements for Quality Management Plans
QA/G-2	Guidance for Preparing Quality Management Plans
QA/G-2C	Guide to Satisfying EPA Quality Assurance Requirements for Contracts
QA/G-2EA	Guide to Implementing Quality Assurance in Extramural Agreements
QA/G-2F	Guide to Satisfying EPA Quality Assurance Requirements for Financial Assistance Agreements
QA/G-3	Guidance for the Management Systems Review Process
QA/G-10	Guidance for Determining Quality Training Requirements for Environmental Data Operations
Project level	
QA/G-4	Guidance for the Data Quality Objectives Process
QA/G-4CS	The Data Quality Objectives Process: Case Studies
QA/G-4D	Data Quality Objectives Decision Errors Feasibility Trials (DEFT) Software
QA/G-4HW	Guidance for the Data Quality Objectives Process for Hazardous Waste Sites
QA/G-4R	Guidance for the Data Quality Objectives for Researchers
QA/R-5	EPA Requirements for Quality Assurance Project Plans
QA/G-5	EPA Guidance for Quality Assurance Project Plans
QA/G-5I	Guidance for Data Quality Indicators
QA/G-5S	Guidance on Sampling Designs to Support Quality Assurance Project Plans
QA/G-5T	Guidance on Specialized Topics in Quality Assurance
QA/G-6	Guidance for the Preparation of Standard Operating Procedures for Quality-Related Operations
QA/G-7	Guidance on Technical Assessments for Environmental Data Operations
QA/G-8	Guidance on Environmental Data Verification and Validation
QA/G-9	Guidance for Data Quality Assessment: Practical Methods for Data Analysis
QA/G-9D	Data Quality Evaluation Statistical Toolbox (DataQUEST).

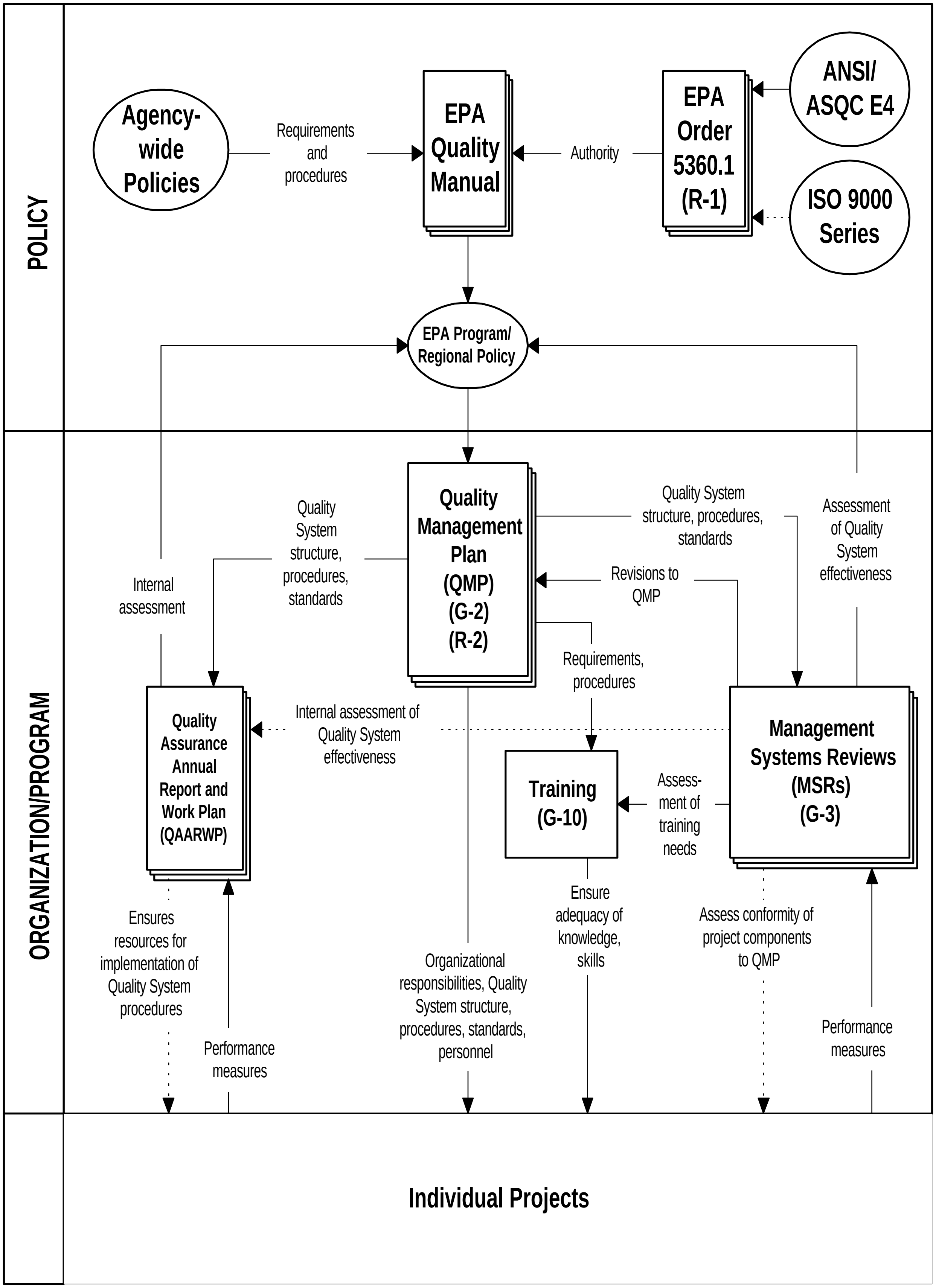

Figure AA1. Relationships Among EPA Quality System Documents at the Program Level

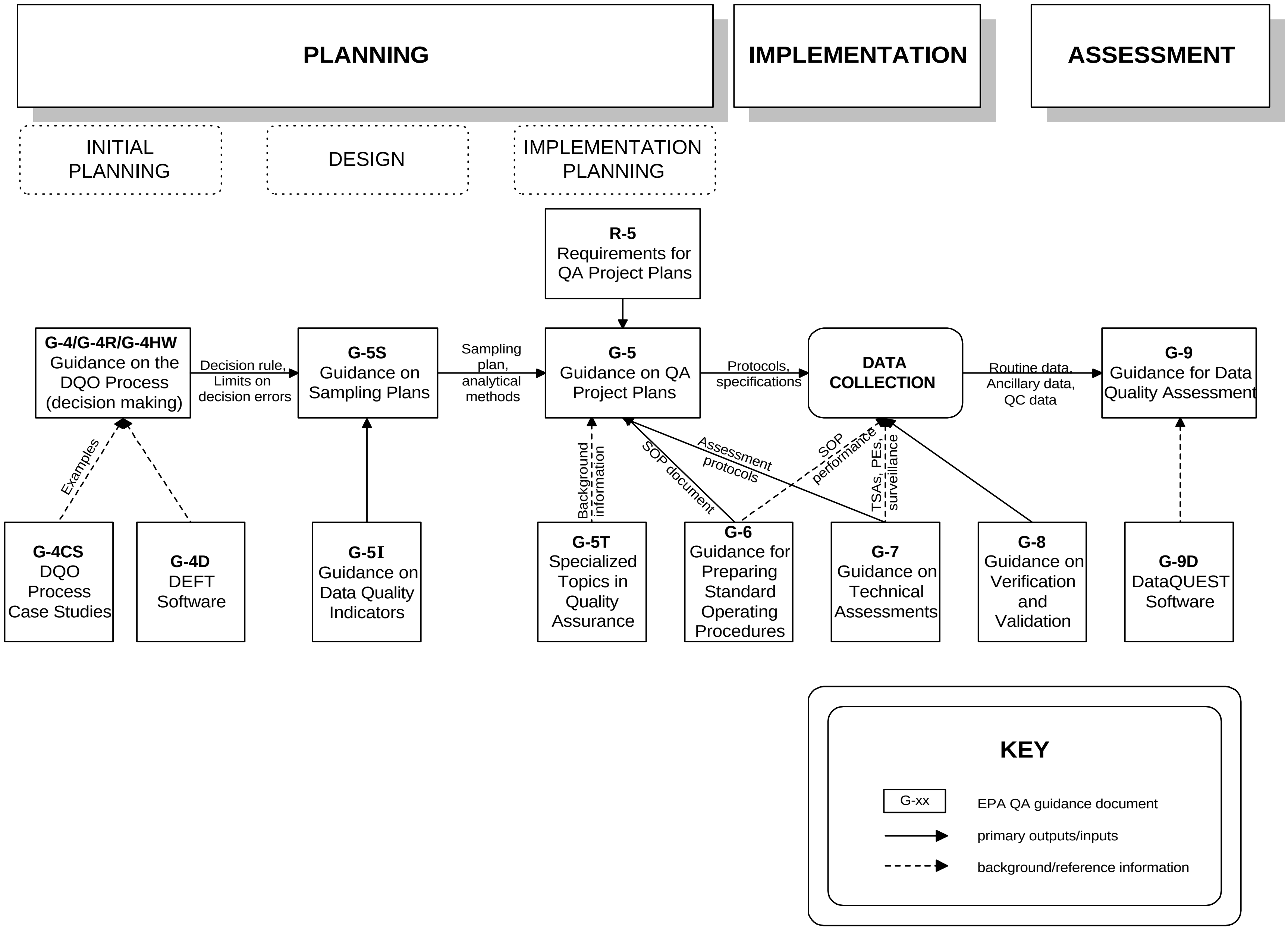

Figure AA2. Relationship Among EPA Quality System Documents at the Project Level